

IMPLICATIONS OF THE CASE

As the first "right to die" case to gain widespread publicity, the Quinlan case profoundly affected medical ethics. It stimulated discussion about ethical dilemmas regarding life-sustaining interventions. The ruling legitimized the idea that life-sustaining interventions might be inappropriate in some situations. The Quinlan court gave judicial support to decision-making by patients, families, and physicians without routine involvement of the courts in cases about life-sustaining treatment. The Quinlan decision also motivated the development of hospital ethics committees. Strictly speaking, the court intended such committees to review prognoses to ensure that patients such as Ms. Quinlan are truly in a PVS. However, the ruling also encouraged physicians and families to use committees to facilitate discussion of the ethical issues raised by such cases. In hindsight, the Quinlan case makes clear that medical judgments about prognosis are fallible. Although Ms. Quinlan's physicians expected her to die after the ventilator was discontinued, she survived for 10 years in a PVS without ventilatory support. Physicians now realize that most patients in a PVS, having intact brainstem function, breathe without assistance.

THE CRUZAN CASE

In the Cruzan case the U.S. Supreme Court issued its first decision on the "right to die (2-5)." The ruling sparked state and federal legislation to encourage the use of advance directives.

THE CASE

Nancy Cruzan was a 33-year-old woman who was in a PVS following an automobile accident in 1983. A month after the accident, a feeding gastrostomy tube was inserted. In 1986, realizing that her condition would not improve, her parents asked that the tube feedings be discontinued. Because the state hospital caring for Cruzan insisted on a court order, the case entered the legal system.

A year before her accident, Cruzan told her housemate that she "didn't want to live" as a "vegetable." If she "couldn't do for herself things alone even halfway, or not at all, she wouldn't want to live that way and she hoped that her family would know that (6)." Cruzan's parents asked that tube feedings be discontinued because they knew "in our hearts" that she would not want to continue living in her condition (6).

THE MISSOURI RULING

The 1988 Missouri Supreme Court ruling in the case severely restricted family decision-making on behalf of incompetent patients (7). Life-sustaining interventions could be withheld only with "the most rigid of formalities," such as a living will or a clear and convincing statement that the patient *would not want the specific intervention in that situation*. The court found no reliable evidence that Nancy Cruzan would have specifically refused artificial feedings. It asserted that Missouri's "unqualified" interest in preserving life, regardless of the patient's prognosis, outweighed any rights an incompetent patient might have to refuse treatment.

THE U.S. SUPREME COURT RULING

By a 5 to 4 vote, the U.S. Supreme Court affirmed the Missouri ruling in 1990 (8). Although competent patients might have a "constitutionally protected liberty interest in refusing unwanted medical treatment," the Court declared that incompetent patients do not have the same right because they cannot exercise it directly. Thus, states may establish "procedural safeguards" governing medical decisions for incompetent patients that are more stringent than requirements for competent patients.

The majority opinion declared that the individual's right to refuse treatment must be balanced against relevant state interests. The Court held that the Constitution allows states to assert an unqualified interest in "the protection and preservation of human life." It ruled that the Constitution also allows states to establish procedures to prevent abuses, to exclude quality of life as a consideration

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in treatment decisions, and to err on the side of continuing life-sustaining treatment. In short, states may require life-sustaining interventions when there is no clear and convincing evidence that the incompetent patient would refuse it. Although the Constitution permits states to rely on family decision-making for incompetent patients, it does not mandate that they do so.

In dissent, Justice William Brennan, joined by Justices Thurgood Marshall and Harry Blackmun, declared that being free of unwanted medical treatment is a fundamental constitutional right that extends to incompetent as well as competent patients and includes refusal of artificial fluid and nutrition. Families or patient-designated surrogates should generally make decisions for incompetent patients. In a separate dissent, Justice John Paul Stevens went further, declaring that the Constitution requires that the best interests of the incompetent patient be followed.

THE DEATH OF NANCY CRUZAN

After the Supreme Court ruling, the Cruzans petitioned the trial court in Missouri to rehear the case because new witnesses had come forward. One woman who worked with Cruzan testified that Cruzan had said that if she were a "vegetable," she would not want to be fed by force or kept alive by machines. Cruzan's attending physician changed his mind and was now in favor of stopping her feedings. The state of Missouri withdrew from further court proceedings, and in December 1990 the judge authorized removal of Cruzan's tube feedings (9).

IMPLICATIONS OF THE CRUZAN CASE

The Cruzan ruling spurred legislation to facilitate the use of advance directives. Many states adopted or revised laws specifically allowing patients to appoint health care proxies. The federal Patient Self Determination Act was enacted and took effect in December 1991. Under this law virtually all hospitals, nursing homes, and health maintenance organizations must at the time of admission give patients written information about their right to provide advance directives.

THE PHYSICIAN-ASSISTED SUICIDE CASES

THE CASES

Competent, terminally ill patients who wanted to end their lives by taking a lethal dose of medications, along with physicians who were willing to write such a prescription, brought court cases in New York and Washington State. These patients had various terminal illnesses, such as cancer, the acquired immunodeficiency syndrome, and emphysema. The plaintiffs asserted that New York and Washington's prohibitions on physician-assisted suicide were unconstitutional.

THE LOWER COURT RULINGS

Two federal appellate courts declared a constitutional right to physician-assisted suicide. The Second Circuit federal court of appeals ruled that New York State violated the Fourteenth Amendment's guarantee of equal protection by allowing terminally ill patients to hasten death by foregoing life-sustaining treatments while forbidding other terminally ill patients to hasten death using a prescription for a lethal dose of medication (10). In the Washington case the Ninth Circuit appeals court declared that physician-assisted suicide was part of a fundamental right, protected by the Fourteenth Amendment's guarantee of liberty, to determine the time and manner of one's death (11).

THE U.S. SUPREME COURT RULINGS

In 1997 the Supreme Court issued a pair of unanimous rulings that held that there is no constitutional right to physician-assisted suicide (12,13). Thus, the Washington and New York laws prohibiting physician-assisted suicide did not violate the Constitution.

The Supreme Court rejected the conclusion that terminally ill patients had a "fundamental liberty interest" in obtaining physician-assisted suicide. According to the Court, states have legitimate reasons for prohibiting assisted suicide (12). These reasons are preserving human life, preventing

suicide, protecting vulnerable groups, protecting the integrity of the medical profession, and avoiding a slippery slope to euthanasia. The Court also ruled that under the Constitution states may permit patients to forego life-sustaining treatment while prohibiting physician-assisted suicide (13). The court declared that the distinction between physician-assisted suicide and withdrawal of life-sustaining treatment is important and logical. When physicians withdraw treatment, they intend only to respect the patient's wishes, not to end the patient's life. Moreover, the cause of death is the underlying fatal disease, not the physician's action.

The Court further declared that the Constitution allows states to prohibit physician-assisted suicide, which intentionally hastens death, while permitting palliative care that might hasten death but is intended to relieve pain (14). According to the Court, the rationale of double effect distinguished the use of high-dose narcotics from euthanasia or assisted suicide. The Court noted that "painkilling drugs may hasten a patient's death, but the physician's purpose and intent is, or may be, only to ease his patient's pain.... The law has long used actors' intent or purpose to distinguish between two acts that may have the same result (14)."

IMPLICATIONS OF THE CASES

The majority opinion concluded that the double effect doctrine provides a rational and constitutional basis for states to allow high-dose narcotics for pain relief in terminally ill patients while prohibiting assisted suicide (15–17). Thus, the majority opinion offers a justification for aggressive palliative care. Three concurring justices went further, suggesting that the Constitution obligates states to permit physicians to provide adequate pain relief at the end of life, even if such care leads to unconsciousness or hastens death. The opinions might help lift legal barriers to palliative care. The Court strongly supported the doctrine of double effect and emphasized the importance of the physician's intention in evaluating the appropriateness of end-of-life care. As Chapter 15 discusses, the Court's reasoning can provide support for the practice of terminal sedation.

THE SCHIAVO CASE

THE CASE

Theresa Schiavo, a 27-year-old woman, suffered a cardiac arrest in 1990 because of potassium abnormalities and lapsed into a PVS. Her husband then won a malpractice suit against the physicians who were caring for her at the time of her cardiac arrest. In 1998, as the legally appointed guardian, her husband asked the court to discontinue tube feedings. Her parents opposed the withdrawal of tube feedings.

THE COURT RULINGS AND THE FLORIDA LAW

The trial court ruled that there was clear and convincing evidence that she would want the feedings discontinued. A long and complicated series of legal disputes ensued. The parents filed various appeals, contending that there was new evidence about her wishes and that her medical condition was misrepresented to the trial court. In 2002 the trial court held a new hearing on her current condition and on whether any new treatments might be effective. That court ruled "the credible evidence overwhelming supports that Terri Schiavo remains in a persistent vegetative state (18)." The court also held that the preponderance of the evidence was that no treatment would significantly improve her quality of life. The parents also claimed that new witnesses would testify that the husband lied about conversations with the patient about her wishes. The court ruled that this new evidence, even if it were accepted as credible, would not meet the legal requirement that the original decision was "no longer equitable (18)."

The state appellate court denied the parents' appeals in four separate rulings. In the fourth ruling the court stated, "It may be unfortunate that when families cannot agree, the best forum we can offer for this private, personal decision is a public courtroom and the best decision-maker is a judge with no prior knowledge of the ward, but the law currently provides no better solution that adequately protects the interests of promoting the value of life (19)." The Florida Supreme Court declined to hear the case.

Pro-life advocates, the Florida legislature, and Governor Jeb Bush then became involved in the case. In 2003 a law called "Terri's law" was enacted authorizing the governor to issue a stay to prevent the withholding of nutrition and hydration from a patient in a PVS who has no written advance directive when a member of the patient's family challenged the withholding of nutrition and hydration. In October 2003, Bush issued such a stay for Ms. Schiavo. In 2004, a Florida court ruled the law was unconstitutional, and the Florida Supreme Court affirmed that decision.

IMPLICATIONS OF THE CASE

Disagreements Among Family Members

The Schiavo case illustrates how intractable and bitter disputes might arise among family members of patients who lack decision-making capacity. Both the husband and the parents accuse each other of acting in bad faith. The courts emphasized the desirability of having a final decision that closed the case. They urged the family to end the dispute and to move forward. However, this case shows how the legal system might not be able to resolve disputes when families are so sharply divided.

Involvement of Third Parties and the Courts

The Schiavo case is unique because of the involvement of pro-life advocacy groups, the Florida legislature, and the governor. Also, the Internet has allowed considerable information about the case to be widely disseminated. However, such involvement of third parties raises several concerns. One is intrusion into the patient's privacy. Ordinarily, decisions about end-of-life care are delegated to families without interference by third parties who have no direct connection with the patient. In polls the overwhelming majority of persons say that they would want decisions to be made by their families rather than by government officials. However, patients might not anticipate that their family might disagree over their care. Second, the public discussion of the case includes many assertions that contradict the court record. For instance, allegations continue to be made that Terri Schiavo is not in a PVS and that new therapies might significantly improve her condition. Both a trial court and an appellate court have determined, however, that she is in a PVS and that the preponderance of credible evidence indicates that no treatment would significantly improve her condition. In addition, allegations have been made that the patient's husband lied about statements she had allegedly made about her wishes for care.

Although society has designated the courts to resolve such difficult disputes, courts might not be able to provide a definitive answer or to resolve ongoing disagreements. The court challenges to "Terri's law" raise fundamental questions about the appropriate role of the legislative and executive branches of government in disputes that cannot be worked out among the family and physicians.

Importance of Advance Directives

Terri Schiavo did not complete an advance directive designating a proxy to make decisions for her; had she done so, the disputes between the parents and husband would likely have been resolved sooner. It is unrealistic to expect a young healthy woman to anticipate the situation Terri Schiavo is now in and to have informed judgments about what she would want done in a catastrophic illness. However, it is not asking too much for a healthy person to appoint a proxy whom she trusts to make decisions for her.

In summary, landmark court cases have helped shape public policy regarding life-sustaining interventions. Physicians need to know enough about these court rulings to correct misunderstandings by patients and colleagues.

REFERENCES

1. In the matter of Karen Quinlan. 70 N.J. 10, 335 A. 2d 647 (1976).
2. Angell M. Prisoners of technology: the case of Nancy Cruzan. *N Engl J Med* 1990;322:1226-1228.
3. Annas G. Nancy Cruzan and the right to die. *N Engl J Med* 1990;323:670-673.
4. Orentlicher D. The right to die after Cruzan. *JAMA* 1990;264:2444-2447.
5. Lo B, Steinbrook R. Beyond the Cruzan case: the U.S. Supreme Court and medical practice. *Ann Intern Med* 1991;114:895-901.

6. Brief for petitioners. *Cruzan v. Missouri Department of Health*; No. 89-1503.
7. *Cruzan v. Harmon*. 760 S.W.2d 408.
8. *Cruzan v. Missouri Department of Health*. 497 U.S. 261, 110 S.Ct. 2841 (1990).
9. *Cruzan v. Harmon*. No. CV384-9P, Circuit court of Missouri (Mo. Cir. Ct. Jasper County Dec 14, 1990) (Teel, J.).
10. *Quill v. Vacco*. 830 F3d 716 (2nd Cir 1966).
11. *Compassion in Dying v. Washington*. 79 F3d 790 (9th Cir 1966) (en banc).
12. *Washington v. Glucksberg*. 117 S.Ct. 2258 (1997).
13. *Vacco v. Quill*. 117 S.Ct. 2293 (1997).
14. *Quill v. Vacco*. 117 S.Ct. 2293 (1997).
15. Alpers A, Lo B. The Supreme Court addresses physician-assisted suicide: can its decisions improve palliative care? *Arch Fam Pract* 1999;8:200-205.
16. Burt RA. The Supreme Court speaks: not assisted suicide but a constitutional right to palliative care. *N Engl J Med* 1997;337:1234-1236.
17. Gostin LO. Deciding life and death in the courtroom. *JAMA* 1997;278:1523-1528.
18. *In re Guardianship of Theresa Marie Schiavo*. No. 90-2908-GB-003 (Fla. Cir. Ct. 2002).
19. *In re Guardianship of Theresa Marie Schiavo*. 851 So. 2d 182 (Fla. 2003).

ANNOTATED BIBLIOGRAPHY

1. Meisel A. *The right to die*, 2nd ed. New York: John Wiley and Sons, 1995.
Comprehensive and lucid treatise on legal rulings on decisions about life-sustaining interventions.
2. Meisel A. A retrospective on *Cruzan*. *Law Med Health Care* 1992;20:340-353.
Reviews legal developments after the 1990 *Cruzan* decision.
3. Burt RA. The Supreme Court speaks: not assisted suicide but a constitutional right to palliative care. *N Engl J Med* 1997;337:1234-1236.
Alpers A, Lo B. The Supreme Court addresses physician-assisted suicide: can its decisions improve palliative care? *Arch Fam Pract* 1999;8:200-205.
Two articles that discuss the important Supreme Court rulings in the two 1997 physician-assisted suicide cases.

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SECTION IV

The Doctor-Patient Relationship

Overview of the Doctor–Patient Relationship

A strong doctor–patient relationship has many dimensions. Physicians have a fiduciary obligation to act in their patients' best interests. To this end, technical expertise and sound clinical judgment are essential. Physicians also should help patients make informed decisions about their care by providing clear information and helping them weigh the pros and cons of alternatives. Physicians should also maintain confidentiality, avoid misrepresentation, and keep promises. Beyond that, patients also want caregivers who have compassion and empathy and who make them feel listened to and cared for. In addition, patients want a primary care physician to guide them through the complicated health care system and coordinate care from specialists, and they also want access to care and continuity of care. They want to be able to see their physician when they need to, and they want a single physician to help them make crucial decisions over the course of an illness.

In modern medicine many incentives encourage physicians to adopt an entrepreneurial approach to their work. The danger of regarding medicine as a business is that many standard business practices might conflict with the goals and ideals of medicine (1). Businesspeople can greatly increase their net income through targeting profitable markets, dropping unprofitable services, and using advertising to increase demand for their product (2). These practices are considered acceptable for people who are selling computers or running a restaurant. However, should physicians or health care organizations offer services only to well-insured patients, drop unprofitable services such as primary care, or increase demand for profitable services that offer little or no benefit to patients? To the extent that health care is considered a need or a right rather than a commodity, such a commercial approach is ethically disturbing. Moreover, medicine as a profession defines itself as putting the patient's interests first (3).

The chapters in this section discuss specific situations in which the doctor–patient relationship is problematic or difficult. Chapter 24 discusses situations in which physicians refuse to care for patients. Doctors might fear that their own health or safety is jeopardized or consider a patient difficult or obnoxious. Chapter 25 discusses the ethical issues that might arise when patients give gifts to their physicians. Chapter 26 analyzes sexual relationships between physicians and patients and discusses how such contact might harm patients. Chapter 27 suggests how physicians should respond when family members or friends provide unsolicited information about a patient and ask that it be kept secret. Chapter 28 analyzes how clinical research, which is essential for medical progress, presents risks to patients who participate in studies. The physician who also is a clinical investigator has additional responsibilities to ensure that the potential benefits of research are proportionate to the risks, to inform patients about the study, and to avoid conflicts of interest.

REFERENCES

1. Kassirer JP. Managed care and the morality of the marketplace. *N Engl J Med* 1995;333:50–52.
2. Jonsen AR. Ethics remain at the heart of medicine: physicians and entrepreneurship. *West J Med* 1986;144:480–483.
3. Medical Professionalism Project. Medical professionalism in the new millennium: a physician charter. *Ann Intern Med* 2002;136(3):243–246.

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Refusal to Care for Patients

Physicians may refuse to care for persons because of an unacceptable threat to their personal safety. In other situations physicians may seek to terminate a counterproductive or an adversarial doctor-patient relationship. The following case illustrates such a refusal to care for a patient.

CASE 24.1 Surgery in an HIV-infected patient.

A 43-year-old man with asymptomatic human immunodeficiency virus (HIV) infection, while crossing a street, is struck by a car running a red light. He suffers a comminuted fracture of the proximal femoral shaft. The surgeons decline to operate because the patient's viral titer has not been checked recently, saying that this fracture can be managed without surgery. Moreover, the surgeons say that in orthopedics operations sharp bone fragments from seropositive patients subject health care workers to an unacceptable risk of lethal illness.

In Case 24.1 standard treatment for this fracture is operative fixation with an intramedullary rod (1). Closed treatment requires several months of traction and has poorer outcomes. Similarly, during the severe acute respiratory syndrome (SARS) epidemic of 2002-2003, some health care workers refused to work with infected patients (2). Although the law generally permits physicians to decide which individuals to accept as patients, it seems inhumane for physicians to refuse crucial medical care to sick persons. This chapter analyzes whether physicians have an ethical obligation to care for patients who are contagious, violent, or uncooperative.

THE CONTEXT OF THE DOCTOR-PATIENT RELATIONSHIP

ETHICAL OBLIGATIONS TO CARE FOR PATIENTS

Physicians present themselves to the public as helpers of the sick and needy, using their expertise for the benefit of patients. The ethical ideal is that patients will receive needed care, even in cases in which the physician might find it risky, difficult, or inconvenient. At the beginning of the HIV epidemic the Surgeon General declared, "Health care in this country has always been predicated on the assumption that somehow, everyone will be cared for, and no one will be turned away. As a physician and an American, I'm proud to be part of a tradition of care that will not abandon the sick or disabled, whoever they are (3)."

In the doctor-patient relationship, the patient's best interests should take priority over the doctor's self-interest (*see* Chapter 4). The guideline of beneficence has several important implications for refusals to care for patients. Physicians should not refuse care to patients whom they dislike or find unpleasant or whose actions, such as smoking, alcohol and substance abuse, or not adhering to medications, make treatment more difficult. It would also be ethically objectionable for physicians

to refuse care to patients on the basis of social class, ethnic background, lifestyle, or political or religious beliefs. Even in war physicians are expected to attend to the sick and injured, regardless of which side they are on. Furthermore, physicians are exhorted to provide needed medical care even to patients whose actions or beliefs they find morally objectionable. Doctors are expected to provide care to the perpetrator of a violent assault as well as to the victim.

This ethical ideal of providing needed care, regardless of the patient's characteristics, has limits. In providing care, physicians are not expected to compromise their own moral or religious beliefs. For example, Catholic physicians are not required to perform abortions. Although physicians are urged to tolerate patient behavior they personally consider immoral, they are not obligated to carry out what they regard as an immoral action. One philosopher has cautioned physicians to distinguish deeply held moral objections from "personal distaste or prejudice (4)." Another acceptable limit is the physician's health and safety. In Case 24.1 the physicians claim that serious personal risks override their ethical obligation to provide care.

LEGAL DEFINITION OF THE DOCTOR-PATIENT RELATIONSHIP

Society as a whole and individual physicians have a moral obligation to care for sick persons, yet doctors generally have no legal duty to provide care. The law generally characterizes the doctor-patient relationship as a contract between autonomous individuals who are free to enter into or break off the relationship, provided that the patient is not abandoned (5). Courts have ruled that physicians have no legal duty to treat new patients who seek care in the absence of an agreement to provide medical care, such as a contract with a health maintenance organization (HMO). For example, it is legal for physicians to have their receptionist schedule new patient appointments only for people with adequate health insurance. Similarly, physicians may restrict the scope of their practice to a particular specialty or range of problems. Thus, an internist would not be expected to perform surgery, just as a psychiatrist would not be expected to treat meningitis.

The legal right to decline to care for patients, however, is limited in many important ways. Employment contracts, as with hospitals or HMOs, may oblige physicians to care for all qualified persons who seek treatment. Similarly, physicians who are on call for a hospital may be required as a condition of staff privileges to provide care to persons who present there. As discussed later in this chapter, emergency departments are required to provide indicated emergency care to patients who seek it.

The Americans with Disabilities Act also forbids physicians from declining to care for patients on the basis of race, sex, national origin, religion, or disability (6). However, physicians and hospitals are not required to provide care when an "individual poses a direct threat to the health or safety of others that cannot be eliminated or reduced by reasonable accommodation (7)." Direct threat refers to "a significant risk of substantial harm," not merely to a "slightly increased risk" or a "speculative or remote risk (8)." The determination of risk must be made according to objective, scientific evidence, not according to the health care worker's subjective judgment. Caring for HIV-infected persons is not considered a "direct threat" to health care workers (8).

OCCUPATIONAL RISKS TO PHYSICIANS

Health care workers might contract serious or fatal contagious diseases on the job. During the SARS epidemic of 2002–2003, a disproportionate percentage of cases and deaths occurred among physicians and nurses caring for hospitalized patients with SARS. Physicians and nurses also feared that their families might become secondarily infected. However, most doctors and nurses cared for patients with SARS despite knowing they were at risk for a potentially fatal disease for which there was no effective treatment and for which preventive measures might be inadequate.

Early in the HIV epidemic fears of occupational HIV infection were widespread. The risk of seroconversion after a percutaneous exposure to the blood of a seropositive patient is 0.3% (9). After mucocutaneous exposure the risk is 0.09% (10). Surgeons and operating room staff are at higher risk for occupational HIV infection than office-based physicians. Later, this risk was reduced through the availability of highly active antiretroviral regimens that could suppress HIV titers in the patient's blood. Moreover, postexposure prophylaxis with antiretrovirals was shown to reduce transmission by 81% (11). In addition, the development of laparoscopic techniques for many operations further reduced risks to surgeons and operating room staff. However, the magnitude of a risk is only

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one component of a person's perception of the risk. The risk of occupational HIV infection and SARS seems especially ominous because these diseases can be fatal, can be transmitted to loved ones, and can be acquired on the job despite precautions.

Other serious infections that can be acquired through occupational exposure are hepatitis C and multidrug-resistant tuberculosis. In addition, angry or psychotic patients might physically threaten or harm health care workers. In one survey, 20% of residents said that they had been physically assaulted during their training (12). Fearful of these serious occupational risks, physicians might be reluctant to provide care to patients they regard as contagious or violent. Avoiding such patients, however, might conflict with their needs for medical care.

RESPONDING TO OCCUPATIONAL RISKS

Acknowledge and Address Fears

Physicians must acknowledge their human fears and limitations; only then are reflection, discussion, and constructive action possible. Fears about safety need to be acknowledged as an understandable human reaction rather than condemned as hysteria (13). In previous epidemics many physicians, including Galen and Sydenham, fled from patients with fatal contagious diseases (14). Health care workers will benefit from having their concerns addressed in a nonjudgmental way.

Some common techniques for encouraging health care workers to accept occupational risks are usually ineffective. Moral exhortations to provide care in risky situations might go unheeded. Indeed, health care workers might be outraged at the suggestion that it is unethical to worry about their personal safety. Reassurance that a risk is low or comparable to other risks frequently proves to be counterproductive (15–17). People reject the suggestion that because they accept risks of greater magnitude, such as the risk of automobile accidents, they should also accept the risk in question (17).

Reduce the Occupational Risks

Hospitals and clinics must provide a safe working environment, which includes protective equipment and instruments such as masks, gowns, and gloves. However, at the onset of an epidemic the best protective measures might not be known. New equipment might need to be developed and made available, such as retractable needles to prevent bloodborne infections. Health care institutions also need policies to protect health care workers, such as having security guards readily available when care is provided to violent patients.

Balance Risks to Health Care Workers and Benefits to Patients

Health care workers should provide care if the medical benefit to the patient is clearly established, substantial, and highly probable, provided that appropriate precautions have been taken to reduce risk. On the other hand, severe risks to health care workers might justify delaying or denying interventions whose benefits are unproved, uncertain, or marginal.

Judgments about the benefits and risks of treatment need to be scientifically sound. In Case 24.1 it would be misleading for physicians to say that operative reduction for this condition is not indicated in seropositive persons. Such surgery is routinely performed for this indication in patients who have other diseases, such as cancer, with poor prognoses. If physicians bias their medical judgments in order to avoid caring for seropositive persons, patients and the public will justifiably question their recommendations on other issues.

DIFFICULT DOCTOR–PATIENT RELATIONSHIPS

Ideally, the doctor–patient relationship is a partnership whose goal is the patient's well-being. In some cases, however, the relationship might be unproductive or adversarial and the physician might consider the patient a "problem" or "difficult" patient (18–20).

CASE 24.2 Disruptive and uncooperative patient.

Ms. W is a 35-year-old woman with end-stage renal disease who repeatedly misses dialysis appointments and requires emergency dialysis. She also does not take her medications regularly or follow her diet, is frequently intoxicated, and disrupts the dialysis unit with her obscene language and attempts to strike

health care workers. Her nephrologist negotiates a contract with her; he agrees to continue to provide dialysis while she agrees keep scheduled appointments, enter substance abuse treatment, follow her diet, take her medications, and seek psychological counseling. When Ms. W does not change her behavior, he notifies her that he will no longer provide chronic dialysis and gives her a list of other nephrologists in the area. When she presents to the emergency department with hyperkalemia and congestive heart failure, the nephrologist considers refusing dialysis (21).

In Case 24.2, Ms. W repeatedly misses appointments, fails to take her medications, and requires emergency care after missing scheduled appointments. Furthermore, she is disruptive, angry, and violent. Physicians commonly view such patients as “bad” patients who have broken the implicit rules of the doctor–patient relationship (20). When providing care, health care workers should not have to suffer verbal or physical abuse and neither should other patients (22). Moreover, health care workers are understandably frustrated when the patient’s own actions bring about or exacerbate medical problems. In addition, such a patient is often considered difficult because he or she provokes such strong negative reactions in health care workers that a therapeutic relationship no longer exists (20). Doctors resent spending so much time and energy on such a patient that they provide insufficient attention to other patients. In less dramatic cases physicians might feel insulted or denigrated by a patient’s racist, sexist, or homophobic comments.

IMPROVING DIFFICULT DOCTOR–PATIENT RELATIONSHIPS

In most cases physicians can find ways to improve a difficult doctor–patient relationship (Table 24-1).

Acknowledge That Problems Exist

The first step is for physicians and patients alike to acknowledge problems. The physician might say, “I sense that both of us are disappointed with how your care is turning out.”

Try to Understand the Patient’s Perspective

Physicians might feel that some patients intentionally vex them, making medical care more difficult. From the patient’s perspective, however, there might be sound reasons for missing appointments, such as difficulties with insurance coverage, transportation, or childcare. Illness might cause patients to feel angry, frustrated, helpless, or out of control. Also, patients might not have control over some behaviors because of substance abuse or psychiatric conditions.

Physicians can elicit patients’ perspectives through open-ended questions about the impact of their illness, competing demands in their life, and barriers to care. Acknowledging a patient’s emotions also encourages further discussion. Once their problems and frustration are acknowledged, patients might be better able to appreciate how their behavior is disrupting their care or the care of other patients. The physician might say, “We’re trying our best to help you, but it’s hard for us if you shout and don’t keep appointments.”

Try to Understand Your Own Responses

Physicians need to understand how their own actions might exacerbate the patient’s behavior. Physicians and nurses who are frustrated and angry at having to provide emergency dialysis might vent their anger on the patient or treat her curtly. Differences in ethnic background, social class, and lifestyle often exacerbate tensions.

TABLE 24-1

Improving Difficult Doctor–Patient Relationships

- Acknowledge that problems exist.
- Try to understand the patient’s perspective.
- Try to understand your own responses.
- Try to negotiate mutually acceptable grounds for continued care.

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Try to Negotiate Mutually Acceptable Plans for Continued Care

Physicians can try to set limits on disruptive behaviors and find mutually acceptable conditions for the doctor-patient relationship (23). A psychiatric or social work consultation can often be helpful. For example, patients might be given more control over some aspects of their care. As in Case 24.2, physicians can warn patients that certain behaviors will lead to termination of the doctor-patient relationship. Doctors can negotiate a formal "contract" that explicitly sets conditions under which the patient and physician will continue the relationship—for example, requiring a family member to accompany the patient to dialysis sessions or having the patient accept treatment for substance abuse and mental illness (21).

In the case of patients who make prejudiced or insulting comments, physicians might need to set limits. If the physician is the brunt of the insult, he or she might say, "It sounds like you're not comfortable with me as your doctor, and I must say that it's hard for me to focus on being a doctor when people make comments like that. I'm willing to try to find a way that we can work together. However, if you want to get care in the clinic here, we ask you not to say things like that." If the doctor is on call and there is no realistic option of getting another doctor, the patient should be told, "I'm the doctor on call tonight. It sounds like you're not comfortable with me as your doctor, and I must say that it's hard for me to focus on being a doctor when you make comments like that. You and I need to work together so that you can get the care you need overnight. How do you think we can do that?"

TERMINATING THE DOCTOR-PATIENT RELATIONSHIP

The patient and physician may agree to transfer the care of the patient to another physician. Physicians may also unilaterally terminate the doctor-patient relationship in certain situations—for example, when Ms. W in Case 24.2 broke her agreement about subsequent behavior and continued to be disruptive and violent. Because termination is a drastic measure, it should be used only as a last resort after attempts to find common ground for ongoing care have failed.

Patient Abandonment

Legally and ethically, physicians may not abandon patients with whom they have established a doctor-patient relationship (21). When terminating a relationship, physicians need to give patients reasonable written notice, so that patients have time to find a new physician and obtain needed care for ongoing medical problems in a timely manner. To help patients find another physician, doctors can give patients a list of other qualified physicians in the area or refer them to the county medical society.

Obligation to Provide Emergency Care

An emergency department is required to provide emergency care to patients who seek it. The public relies on emergency departments and physicians to provide proper emergency treatment and expects them to do so. Delays in emergency care might seriously harm patients. Furthermore, once emergency departments begin a medical evaluation, patients justifiably rely on them to provide proper care.

The federal Emergency Medical Treatment and Labor Act (EMTALA) prohibits emergency departments from transferring patients in unstable condition who need emergency care as well as pregnant women in active labor (24). Every person seeking treatment in an emergency department must receive a screening examination. If the patient is found to have an emergency condition, the hospital must provide treatment to stabilize the patient's condition, within the constraints of the available staff and facilities.

Thus, if Ms. W in Case 24.2 presents to the emergency department with life-threatening hyperkalemia and congestive heart failure, emergency dialysis must be provided (22). This requires a nephrologist and dialysis nurse. Therefore, the health care workers who refuse to provide chronic dialysis might still have to perform emergency dialysis. Sometimes different individuals or institutions can share the emergency care of such patients.

In summary, physicians have an ethical obligation to care for patients even at some annoyance or personal risk. Before unilaterally terminating a difficult doctor-patient relationship, physicians should try both to understand the patient's perspective and to find some mutually acceptable arrangement for continuing care.

REFERENCES

1. Skinner HB, ed. *Current diagnosis and treatment in orthopedics*, 3rd ed. New York: Lange Medical Books/McGraw-Hill, 2003.
2. Sibbald B. Right to refuse work becomes another SARS issue. *CMAJ* 2003;169:141.
3. Koop CE. Testimony before Presidential Commission on AIDS. 1987 September 8.
4. Jonsen A, Siegler M, Winslade W. *Clinical ethics*, 3rd ed. New York: Macmillan, 1991:73-74.
5. Annas GJ. Not saints, but healers: the legal duties of health care professionals in the AIDS epidemic. *Am J Public Health* 1988;78:844-849.
6. Americans with Disabilities Act of 1990. 42 USC §§12181,12182.
7. Americans with Disabilities Act Public Accommodation Regulations. 28 CFR § 36.201.
8. Gostin LO, Feldbaum C, Webber DW. Disability discrimination in America: HIV/AIDS and other health conditions. *JAMA* 1999;281:745-752.
9. CDC. Updated public health service guidelines for management of health care worker exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR* 2001;50:1-52.
10. Gerberding JL. Clinical practice. Occupational exposure to HIV in health care settings. *N Engl J Med* 2003;348(9):826-833.
11. CDC. Case-control study of HIV seroconversion in health-care workers after exposures to HIV-infected blood—France, United Kingdom and United States, January 1988–August 1994. *MMWR* 1995;44(50):929-933.
12. Cook DJ, Liutkus JF, Risdon CL, et al. Residents' experiences of abuse, discrimination and sexual harassment during residency training. McMaster University Residency Training Programs. *CMAJ* 1996;154:1657-1665.
13. Gerbert B, Maguire B, Badmer V, et al. Why fear persists: health care professionals and AIDS. *JAMA* 1988;260:3481-3483.
14. Zuger A, Miles SH. Physicians, AIDS, and occupational risk. Historic traditions and ethical obligations. *JAMA* 1987;258:1924-1928.
15. Nelkin D. Communicating technological risk: the social construction of risk perception. *Ann Rev Public Health* 1989;10:95-113.
16. Slovic P. Perception of risk. *Science* 1987;236:280-285.
17. National Research Council. *Improving risk communication*. Washington: National Academy Press, 1989.
18. Groves JE. Taking care of the hateful patient. *N Engl J Med* 1978;298:883-887.
19. Drossman DR. The problem patient: evaluation and care of medical patients with psychosocial disturbances. *Ann Intern Med* 1978;88:366-372.
20. Stokes T, Dixon-Woods M, McKinley RK. Breaking up is never easy: GPs' accounts of removing patients from their lists. *Fam Pract* 2003;20(6):628-634.
21. Orentlicher D. Denying treatment to the noncompliant patient. *JAMA* 1991;265:1579-1582.
22. Friedman EA. Must we treat noncompliant ESRD patients? *Semin Dial* 2001;14(1):23-27.
23. Quill TE. Partnerships in patient care: a contractual approach. *Ann Intern Med* 1983;98:228-234.
24. 42 U.S.C. § 1395dd.

ANNOTATED BIBLIOGRAPHY

1. Annas GJ. Not saints, but healers: the legal duties of health care professionals in the AIDS epidemic. *Am J Public Health* 1988;78:844-849.
Discusses how physicians have no legal duty to treat patients in most situations despite a strong moral duty to do so.
2. Cantor J, Baum K. The limits of conscientious objection—may pharmacists refuse to fill prescriptions for emergency contraception? *N Engl J Med* 2004;351:2008-12.
Argues that institutions should make reasonable attempts to accommodate health care workers' refusals to provide care based on conscience but that patients should be referred to other facilities that will provide care.
3. Friedman EA. Must we treat noncompliant ESRD patients? *Semin Dial* 2001;14:23-27.
Discusses legal, ethical, and clinical aspects of denying treatment to noncompliant, abusive, violent dialysis patients.
4. Gostin LO, Feldbaum C, Webber DW. Disability discrimination in America: HIV/AIDS and other health conditions. *JAMA* 1999;281:745-752.
Summary of disability law that explains that physicians may decline to care for infectious patients only if there is a significant risk of substantial harm.

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Gifts from Patients to Physicians

Modest gifts from patients, such as holiday cards, cookies or candy, flowers, and toys for children, gratify physicians and allow patients to express their appreciation. Other gifts, however, can cause problems. Expensive gifts might compromise the physician's judgment. Very personal gifts imply more than a professional relationship. Physicians might find that a gift from a patient makes them uncomfortable, and they might be uncertain how to respond.

Gifts from patients are often considered simply matters of social convention and etiquette, not ethics. This chapter points out how gifts from patients might raise ethical issues because they might change the doctor-patient relationship, impair clinical judgment, or erode public trust. Because physicians often find it embarrassing to discuss gifts, this chapter also suggests how to respond to problematic gifts from patients.

REASONS FOR PATIENTS TO GIVE GIFTS TO PHYSICIANS

TO THANK PHYSICIANS

Patients commonly send gifts to express appreciation to physicians for their care. Patients who have recovered from serious illness are understandably grateful to their physicians, particularly if the diagnosis was difficult, the treatment was complicated, or the physician was particularly supportive or involved.

TO SATISFY THEIR OWN NEEDS

Gifts might also reflect the patient's psychological needs.

CASE 25.1 Cookies from a lonely elderly patient.

A 74-year-old widow has hypertension, osteoarthritis, and mild depression. She has no surviving relatives, few friends, and few social activities. A new resident takes over her care. She talks about her sadness and emptiness, and he encourages her to attend a senior center. On the next visit she brings him a box of home-baked cookies.

For lonely patients, their physician might be one of the few people who listen or pay attention to them. Bringing a gift might give them a sense of purpose or alleviate their loneliness. Taking initiative and showing concern for other people might be therapeutic for them. For other patients, giving physicians small gifts allows them to make a personal connection to an otherwise impersonal medical care system.

TO ENHANCE FUTURE CARE

In a few cases gifts might represent expectations for future care rather than thanks for past efforts. Patients might feel that bestowing a gift will gain them special consideration. For instance, some patients might want to have the last appointment of the day because of difficulties getting off from work. Other patients might hope that gifts will gain them timely appointments or faster responses to phone calls. In rare cases patients who give gifts might subsequently ask physicians to do something that is ethically questionable.

CASE 25.2 Request for disability certification.

A patient with mild asthma gives his physician a toy for his son at Christmas. The next month he asks the physician to complete a form for a disability parking sticker. The patient does not meet the objective criteria for hypoxemia or dyspnea listed on the form.

In Case 25.2 the timing of the gift and the request are disturbing. The physician might feel manipulated because an apparently thoughtful gift might have had strings attached. Deceiving third parties about a patient's condition is ethically problematic (see Chapter 6). To do so after receiving a gift would appear like accepting a bribe.

TO MEET CULTURAL EXPECTATIONS

In some cultures gifts to physicians or other healers are routinely expected. Such gifts might show respect or be considered an essential aspect of the healing process. In some societies bribery might be necessary to ensure access to care. Physicians need to consider whether gifts might have special cultural significance for patients and correct any misconceptions about the U.S. medical care system.

PROBLEMS WITH GIFTS

It is human nature for patients who have given gifts to expect some consideration in return, either consciously or unconsciously (1). However, some gifts might create ethical problems because of patients' inappropriate expectations.

EXPECTATIONS FOR PERSONAL TREATMENT

Some patients might believe that gifts entitle them to special treatment, such as more convenient or prompter appointments. Other patients might expect freedom to call the physician at home or to have medications refilled over the telephone without an office visit. Even apparently small gifts might be problematic if such expectations become burdensome to physicians. For example, physicians understandably want to limit add-on appointments and after-hours phone calls in order to reduce personal stress and to protect their family life, yet they might find it difficult to refuse a request from a patient who has given a gift.

CHANGES IN THE DOCTOR-PATIENT RELATIONSHIP

Some gifts might change the doctor-patient relationship inappropriately.

CASE 25.1 continued. Focus on the physician's problems rather than the patient's.

The lonely, elderly patient starts to bring cookies or other gifts of food at every visit. Moreover, visits now focus on the physician rather than on the patient. The patient inquires about what foods the physician likes so that she can plan her next gift. She also expresses concern about whether he is getting enough sleep and has enough time off.

In Case 25.1 an overworked and underappreciated house officer might be delighted that someone takes a personal interest in him, but it is problematic if the physician assumes the role of a surrogate grandchild. Patient visits should focus on the patient's problems, not the physician's. The physician might miss opportunities to encourage and reinforce the patient's efforts

to become more socially active in the community. In the long run it is counterproductive and unrealistic for lonely patients to depend totally on the medical system for their emotional and social needs.

In other circumstances gifts violate the boundaries of the professional relationship. An extreme example might be the gift of lingerie or other intimate apparel. Such gifts imply a personal relationship, not a professional one. Patients who overstep the boundaries of a professional relationship are acting out their own needs or fantasies. Not only should such gifts be refused but also appropriate boundaries need to be promptly and firmly reestablished. After such a gift, a physician who feels uncomfortable continuing the doctor-patient relationship might need to arrange to transfer care to another physician.

IMPAIRMENT OF CLINICAL JUDGMENT

Gifts can create or strengthen personal ties, but too close a relationship might be undesirable. It is difficult to provide care to a close relative because emotional ties might cloud clinical judgment (2). In a similar way, gifts that establish or imply a very close personal relationship might compromise the physician's judgment. Expectations of special treatment might compromise care, as when a patient expects the physician to diagnose and treat a complicated problem on the basis of a telephone call rather than an office visit. Psychologically, it is difficult to say no to patients who have given gifts, even if they request interventions that are unsound medical practice or not in their best interests. Similarly, a gift from a seriously ill patient might be problematic if it leads the physician to misrepresent bad news or causes the patient to develop unrealistic expectations.

EROSION OF PUBLIC TRUST

The doctor-patient relationship might be weakened if other patients believe that they will receive second-class care unless they offer gifts. Physicians serve as gatekeepers, allocating appointments, their time and attention, and, in managed care systems, health care resources. Generally, phone calls or appointments are allocated primarily on the basis of patient need. It would damage both the individual physician and the profession as a whole if patients believed that the best way to get the physician's attention is through a gift. Even a perception that physicians are allocating their efforts on the basis of favoritism would erode public trust.

SOLICITING GIFTS

Although this chapter has focused on gifts that patients offer to physicians, solicitation of gifts by physicians also merits attention. It is unethical for physicians to solicit personal gifts in return for services rendered because physicians' fees should be adequate compensation for their services. It might also be problematic for physicians to solicit contributions for some cause, such as a hospital or a political movement. Such solicitations might seem a natural way for physicians to work for causes they believe in, but patients might not feel free to decline the solicitation if their physician solicits it personally and therefore knows whether they have responded. They might fear that the physician will not render prompt or meticulous care in the future if they refuse.

HOW TO RESPOND TO GIFTS FROM PATIENTS

In responding to gifts physicians need to take into account the nature of the gift and the circumstances.

ACCEPT APPROPRIATE GIFTS GRACIOUSLY

In most cases gifts from patients are well intentioned and appropriate and should be accepted graciously. Indeed, many patients would feel insulted if physicians did not accept homemade cookies, toys for Christmas, or clothes for a new baby. Similarly, it would be unfeeling not to accept a small gift after the physician has devoted a great deal of effort in helping a patient recover from a difficult illness.

DO NOT LET GIFTS GO TO YOUR HEAD

Physicians should not allow gifts from patients to give them an exaggerated sense of their importance or their skill. Many patients, because they are sick and dependent, are extremely grateful for competent, humane care. It is gratifying that such qualities in physicians are recognized and reinforced, but physicians should appreciate that they might not have done anything extraordinary, just provided standard care.

APPRECIATE THAT SOME GIFTS ARE PROBLEMATIC

Some gifts might seem disproportionate to the services rendered (3).

CASE 25.3 Tickets to an opera.

A 52-year-old businessman establishes care with a new physician. At the first visit they discuss preventive measures such as exercise and diet. The next week the businessman offers the physician opera tickets to the opening night gala.

Intuitively, some gifts seem out of proportion to what the physician has done. Most physicians would feel comfortable accepting gifts worth less than \$20, but many would feel uncomfortable accepting \$1,000 tickets to the opening night of an opera after a routine new patient visit. Even if a wealthy patient considers this a small gift, it might give the wrong impression to other patients. Furthermore, the physician might wonder whether such a lavish gift reflects unrealistic expectations for care. Finally, many physicians feel uncomfortable accepting cash gifts because they seem associated with commerce and profits.

GET ADVICE ABOUT THE GIFT

Most physicians, even if they are uncomfortable about gifts, hesitate to discuss them with colleagues. Physicians might not appreciate that many colleagues also feel awkward and uncertain about gifts. Other people, however, can help the physician interpret the significance of gifts and understand the patient's possible expectations. In judging a gift's appropriateness, physicians can apply a practical rule of thumb: How would colleagues and other patients react if they knew about the gift? If other patients would question the gift, it is best not to accept it.

CONSIDER SHARING THE GIFT WITH OTHERS

Concerns about gifts can often be prevented or resolved by sharing the gift with others and letting the patient know. For example, the physician might donate the gift to charity or share it with other staff who care for the patient. Homemade cookies and cakes can be shared with office staff. Monetary gifts can be given to a house staff fund for refreshments or books, to the hospital volunteer fund, or to a medical charity. The physician should let the patient know how the gift was distributed and explain why this was done. Such sharing acknowledges the patient's thoughtfulness while making it less likely that the patient will feel entitled to special care from the physician.

DECLINE GIFTS WITHOUT REJECTING THE PATIENT

Even when physicians believe that declining a gift is appropriate, they might find it awkward to do so. Several strategies might allow the physician to decline the gift while respecting the patient's feelings. In each approach physicians should start by saying that they are grateful and touched. One approach is to explain that accepting such a gift might compromise the physician's ability to give high-quality care in the future. Although this approach is straightforward, patients often protest that they would never ask for special consideration. A second approach is to decline the gift politely but firmly without giving more specific reasons. Physicians might simply say that they could not possibly accept the gift and that their policy is not to accept such gifts, even though they are touched by the thoughtfulness. This strategy often works in conjunction with telling the patient that the gift will be shared with others.

If the physician suspects that gifts reflect the patient's social isolation or other needs, as in Case 25.1, these issues should be addressed separately during patient visits.

WHAT IF THE PATIENT LATER REQUESTS SPECIAL TREATMENT?

After a gift the patient might later request special treatment. A practical guideline is for physicians to do what they would have done if the same request had come from a patient who had not given a gift (3).

In conclusion, gifts from patients strengthen social relationships and expectations. Usually, gifts are thoughtful gestures of appreciation that should be accepted graciously. Some gifts, however, can be problematic. Discussing gifts with colleagues and considering how other patients would react might help physicians respond to them appropriately.

REFERENCES

1. Murray TH. Gifts of the body and the needs of strangers. *Hastings Cent Rep* 1987;17:30-38.
2. LaPuma J, Priest ER. Is there a doctor in the house? An analysis of the practice of physicians treating their own families. *JAMA* 1992;267:1810-1812.
3. Lyckholm LJ. Should physicians accept gifts from patients? *JAMA* 1998;280:1944-1946.

ANNOTATED BIBLIOGRAPHY

1. Lyckholm LJ. Should physicians accept gifts from patients? *JAMA* 1998;280:1944-1946. Brief, thoughtful review of the topic.

Sexual Contact between Physicians and Patients

The Hippocratic Oath forbids sexual relationships between physicians and patients. Some people, however, believe that this prohibition is no longer appropriate: Sexual mores have changed, and sexual relationships between consenting adults should be considered private. This chapter argues that sexual contacts between physicians and patients are unethical if they take advantage of patients' trust, dependency, and vulnerability.

PREVALENCE OF SEXUAL CONTACT BETWEEN PHYSICIANS AND PATIENTS

In a national survey 9% of physicians reported at least one sexual contact with a patient or former patient (1). Most cases involved male physicians and female patients. This study excluded cases in which the sexual relationship preceded the medical care, such as the provision of medical care to a spouse. Twenty-three percent of respondents said that one or more of their patients had revealed sexual contact with a previous physician. In other studies between 5% and 10% of psychiatrists and other mental health professionals admitted to sexual contact with patients (2).

JUSTIFICATIONS FOR SEXUAL CONTACT BETWEEN PHYSICIANS AND PATIENTS

Several justifications are commonly offered for relaxing the traditional prohibition on sexual contacts between physicians and patients (3).

RESPECT FOR PRIVACY

Generally, sexual relationships between consenting adults are considered private matters with which other people and society have no right to interfere. To many it makes no difference that the partners are physician and patient. In this view it is demeaning and unrealistic to view patients as so vulnerable that they cannot make their own decisions about their private lives. Accordingly, restricting freedom to enter into sexual relationships would be paternalistic and intrusive.

LACK OF HARM TO PATIENTS

Many people believe that patients are no more likely to be harmed in sexual relationships with their physicians than they are in other sexual relationships. In the United States short-term relationships and divorces are common. Anecdotally, many people know of happy marriages between physicians

and former patients. In this view, even if some sexual relationships with physicians harm patients, there is no reason to prohibit all such relationships.

LACK OF SOCIAL OPPORTUNITIES FOR PHYSICIANS

In small towns and rural areas a physician might care for a large proportion of the community. Social opportunities for physicians would be very limited if romantic and sexual relationships with patients were barred.

OBJECTIONS TO SEXUAL RELATIONSHIPS WITH CURRENT PATIENTS

Professional codes of ethics consider sexual relationships with current patients unethical. The American Medical Association (AMA) recently declared, "Sexual conduct or a romantic relationship with a patient concurrent with the physician-patient relationship is unethical (2)." Patients might feel "angry, abandoned, humiliated, mistreated, or exploited by their physicians. Victims have been reported to experience guilt, severe mistrust of their own judgment, and mistrust of both men and physicians (2)." There are several reasons for such role-specific restrictions on physicians (Table 26-1).

PHYSICIANS SHOULD NOT TAKE ADVANTAGE OF THE DOCTOR-PATIENT RELATIONSHIP

It might be difficult for patients to make truly autonomous decisions on sexual relationships with physicians. The physician-patient relationship arises from the patient's illness, which can cause patients to be vulnerable and dependent (4). Patients usually place great weight on their physicians' advice and judgment and naturally develop feelings of trust, gratitude, and admiration toward physicians. Unconsciously, the patient might mistake such feelings for romantic or sexual attraction. Patients as well as physicians might not appreciate how such positive feelings result from the doctor's role as well as the doctor's personal attributes. Although such transference has been most clearly described in patients undergoing psychotherapy, similar feelings might occur in all physicians-patient relationships. Physicians might also misinterpret their own feelings of caring and concern for patients, which are a natural part of the doctor-patient relationship, as romantic or sexual attraction.

In the course of a professional relationship, patients make intimate revelations to physicians, as in the following case.

CASE 26.1 Current patient receiving active therapy.

A 45-year-old male physician is treating a 32-year-old woman for depression and peptic ulcer disease. The woman reveals that she was sexually abused as a child. The physician, who is going through a divorce, finds her attractive and considers initiating a romantic and sexual relationship with her.

TABLE 26-1

Objections to Sexual Relationships with Current Patients

Physicians should not take advantage of the doctor-patient relationship.

Physicians have power over patients.

Trust in the profession will be undermined.

Some patients are particularly vulnerable.

In Case 26.1 a depressed patient discloses private information, which she might not have told anyone else. In their professional role, physicians are privy to intimate personal information. During the medical history physicians may take a detailed sexual history. Patients may reveal their innermost fantasies and fears. Patients undress for examinations and allow physicians to touch them and even invade their bodies during medical or surgical procedures. Such intimacy within the doctor-patient relationship is one-sided. Physicians do not ordinarily reveal their personal feelings, thoughts, or bodies to patients. Thus, physicians know much more personal information about patients than patients know about them. Physicians might betray the patient's trust if they take advantage of such intimate information, either consciously or unconsciously, in pursuing sexual relationships with patients.

PHYSICIANS HAVE POWER OVER PATIENTS

Physicians have power over patients that they can use to their advantage in sexual relationships. Inequalities in power might make it more difficult for patients to decline sexual relationships with them than with other people. In Case 26.1 the very framing of the issues implies unequal power: The physician considers initiating a sexual liaison, as if it were inconceivable that the patient would refuse. Because physicians order tests and treatments and schedule appointments, they control patients' access to medical care. There might be an implied or inferred threat that if the patient does not agree to sexual contact, the doctor-patient relationship will be terminated (5). Physicians might also provide false reassurance to patients that an effective therapeutic relationship can continue even if a sexual liaison is initiated (5). In egregious cases the physician might portray a sexual liaison as part of medical therapy.

TRUST IN THE PROFESSION WILL BE UNDERMINED

If the profession were to condone sexual relationships with patients, the public might begin to believe that physicians are motivated by self-interest and are willing to take advantage of patients. Patients might be reluctant to visit physicians or discuss intimate matters. Patients with psychiatric or gynecological problems might be particularly deterred from seeking care.

SOME PATIENTS ARE PARTICULARLY VULNERABLE

Some patients might be especially harmed in sexual relationships with physicians. In Case 26.1 the patient's depression might compromise her ability to consent freely to a sexual relationship. Furthermore, patients who have suffered incest or rape might find it difficult to refuse sexual relationships with authority figures and might feel particularly betrayed if the current relationship repeats previous traumatic experiences. Such persons might not even be aware that they are repeating a previous pattern of behavior.

THE PATIENT'S MEDICAL CARE MIGHT BE COMPROMISED

When physicians provide care to a spouse, they might not be thorough in taking a history, conducting an examination, or ordering diagnostic tests (6). Similarly, providing medical care to a sexual partner might lead to suboptimal care. When physicians are having a sexual relationship with patients, their clinical judgment is likely to be compromised (7). They might not be thorough in taking a history, conducting an examination, considering certain diagnoses, or ordering diagnostic tests.

LEGAL ISSUES

Sexual relationships between physicians and current patients might lead to criminal charges or to disciplinary action by licensing boards (8-10). Physicians might also face civil suits for malpractice. Malpractice insurers might exclude coverage for civil claims relating to sexual misconduct, asserting that such behavior is not part of providing medical care.

COMPARISON

In other professions criticized for covering up offending priests have been criticized for medicine, the church with clients.

SEXUAL RELATIONSHIPS

Although sexual relationships are less agreement about 94% of physicians and 36% of physicians.

CASE 26.2 Form

A female emergency room nurse. Several years later she says that they share a relationship because of their professional relationship.

In Case 26.2 more, the patient not particularly vulnerable as for any other case. Feelings of dependence.

CASE 26.3 Rece

A male surgeon. During his private visits he finds that the patient is appreciative of his postoperative visits.

In Case 26.3 emergency surgery. Independent judgment. Other men she knew.

About former patients. Also unethical. From the previous dependency in the relationship.

TERMINATION

Termination of the relationship. Its, telephone counseling tests. In addition, partner as his sexual relationship.

NATURE OF

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COMPARISONS WITH OTHER PROFESSIONS

In other professions sexual relationships with clients are also condemned. Churches are strongly criticized for covering up sexual relationships between clergy and parishioners and transferring offending priests or ministers without appropriate disciplinary action. Similarly, lawyers have been criticized for sexual relationships with clients, particularly clients in divorce cases. As in medicine, the charge is that these professionals abuse their trust and power in sexual relationships with clients.

SEXUAL RELATIONSHIPS WITH FORMER PATIENTS

Although sexual relationships with current patients are generally considered inappropriate, there is less agreement about relationships with previous patients. In the previously cited survey, although 94% of physicians considered it unethical to have sexual relationships with current patients, only 36% of physicians considered it unethical to have sexual relationships with former patients (1).

CASE 26.2 Former patient, with no ongoing relationship.

A female emergency physician treats a 28-year-old man who requires a tetanus shot for a foot injury. Several years later they meet again as single parents whose children are in the same school. They discover that they share many interests. The physician wonders if a romantic relationship would be unacceptable because of their previous professional relationship.

In Case 26.2 it is unlikely that the former patient feels dependent on the physician. Furthermore, the patient revealed little personal information during the doctor-patient relationship and is not particularly vulnerable on that basis. A relationship between equals seems as possible for them as for any other couple.

Feelings of dependency, however, might persist after care is terminated, as in the following case.

CASE 26.3 Recent surgical patient.

A male surgeon performs an emergency laparotomy on a woman with appendicitis. During postoperative visits he finds himself spending much more time with her than he usually does with patients. She is appreciative of his attention and solicitous about his long hours and fatigue. A month after her final postoperative visit, he invites her to dinner.

In Case 26.3 the patient might have strong feelings of gratitude and dependency soon after emergency surgery. Unlike Case 26.2, it might be more difficult for the patient to make an independent judgment about a relationship or to decline invitations from the surgeon, compared with other men she knows.

About former patients, the AMA states, "Sexual or romantic relationships with former patients are also unethical if the physician uses or exploits trust, knowledge, emotions, or influence derived from the previous professional relationship (2)." Thus, it is important to identify situations in which dependency in doctor-patient relationship continues (11). Several factors should be considered.

TERMINATION OF MEDICAL CARE

Termination of care and absence of contact should be complete, including cessation of office visits, telephone consultations, prescriptions, and reminder postcards about appointments or screening tests. In addition, a new physician should be identified so that the patient no longer regards the partner as his or her physician. The purpose of terminating care should not be the initiation of a sexual relationship.

NATURE OF THE DOCTOR-PATIENT RELATIONSHIP

Some types of medical care are so intimate that the doctor-patient relationship might never be completely ended. Counseling and therapy might evoke powerful feelings of transference that last for years. Patients might have intense feelings of dependency and gratitude toward physicians

years after therapy has been terminated. The American Psychiatric Association considers any sexual contact with a former psychiatric patient as unethical. Some patients might be particularly vulnerable because of past victimization (12). In specialties such as surgery or gynecology, which involve unique and intimate physical contact, the patient might still regard the physician as being in that role years later. In contrast, in Case 26.2 tetanus immunization is so routine that any feelings of dependency in the patient are likely to be transient and weak. In that situation the patient's dependence on the physician might be similar to dependence on a librarian.

TIME SINCE LAST MEDICAL CARE

In Case 26.3, during the immediate postoperative period the patient's feelings of vulnerability and dependency undoubtedly continue. Amorous advances by the physician might take advantage of these feelings in the patient. The passage of time helps extinguish feelings of dependency toward physicians and reduces the risk that physicians will abuse their power in initiating sexual relationships with patients (5). To prevent abuse, the Ontario College of Physicians and Surgeons Task Force recommends a waiting period of 2 years since the last episode of patient care, with no contact in the interim (13). The crucial issue, however, is not simply the amount of time but rather the lack of a continuous relationship and the "potential for misuse of emotions derived from the former professional relationship (2)."

CIRCUMSTANCES OF RENEWAL OF CONTACT

If the doctor and former patient renew their acquaintance in a medical context, the patient might resume his or her previous role as dependent patient. On the other hand, the physician and former patient might meet again in a nonmedical context, as in Case 26.2. Being reacquainted in a nonmedical setting makes it more likely that the relationship is not colored by the previous doctor-patient relationship.

SUGGESTIONS

Physicians who are considering sexual relationships with current or former patients might consider the following suggestions.

RECOGNIZE EARLY SIGNS OF ROMANTIC INTEREST

Rarely are sexual or romantic feelings so overwhelming that the physician is swept away by uncontrollable passion. Physicians should be alert to early signs of romantic feelings for a patient. For example, they might look forward to the next visit or pay particular attention to their appearance on the day of the patient's visit. Sexual misconduct often begins with seemingly minor violations of the boundaries of the doctor-patient relationship, such as talking about the physician's problems rather than the patient's or scheduling appointments outside office hours (7). Recognizing these early symptoms gives physicians time to act thoughtfully and to consider the potential problems (9).

SEEK ADVICE

It is hard to think critically about romantic or sexual interests. The AMA recommends that "it would be advisable for a physician to seek consultation with a colleague before initiating a relationship with a former patient (2)." Confidential advice can provide an honest appraisal of the potential harm to the patient, the physician, and the medical profession. Such counsel might be a safeguard for physicians who might otherwise act impulsively. Although discussing such an intimate decision with other people might seem intrusive, such sexual relationships are not completely private if they harm patients or undermine public trust in the medical profession.

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5. LaPuma J
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RESPONDING TO ADVANCES BY PATIENTS

In some cases the patient, not the physician, takes the initiative in pursuing a romantic or sexual liaison. However, physicians might still be considered responsible because they are in a better position than patients to recognize the potential harms of such relationships. In medical decisions physicians do not simply accede to a patient's requests or demands. Physicians have an ethical duty to act in patients' best interests, even if it clashes with their own self-interest.

In summary, patients naturally feel trust, dependency, and gratitude toward their physicians. Sexual relationships with current patients exploit such feelings and are unethical. Sexual relationships with former patients are also unethical to the extent that the physician takes advantage of emotions and influence deriving from the doctor-patient relationship.

REFERENCES

1. Gartrell NG, Milliken N, Goodson WH, et al. Physician-patient sexual contact: prevalence and problems. *West J Med* 1992;157:139-143.
2. Council on Ethical and Judicial Affairs of the American Medical Association. Sexual misconduct and the practice of medicine. *JAMA* 1991;266:2741-2745.
3. Appelbaum PS, Jorgenson LM, Sutherland PK. Sexual contact between physicians and patients. *Arch Intern Med* 1994;154:2561-2565.
4. Pellegrino ED, Thomasma DG. *For the patient's good: the restoration of beneficence in health care*. New York: Oxford University Press, 1988.
5. Appelbaum PS, Jorgenson L. Psychotherapist-patient sexual contact after termination of treatment: an analysis and proposal. *Am J Psychiatry* 1991;148:1466-1473.
6. LaPuma J, Priest ER. Is there a doctor in the house? An analysis of the practice of physicians' treating their own families. *JAMA* 1992;267:1810-1812.
7. Gabbard GO, Nadelson C. Professional boundaries in the physician-patient relationship. *JAMA* 1995;273:1445-1449.
8. Johnson SH. Judicial review of disciplinary action for sexual misconduct in the practice of medicine. *JAMA* 1993;270:1596-1600.
9. Gutheil TG, Gabbard GO. Misuses and misunderstandings of boundary theory in clinical and regulatory settings. *Am J Psychiatry* 1998;155(3):409-414.
10. Dehlendorf CE, Wolfe SM. Physicians disciplined for sex-related offenses. *JAMA* 1998;279(23):1883-1888.
11. Malmquist CP, Notman MT. Psychiatrist-patient boundary issues following treatment termination. *Am J Psychiatry* 2001;158(7):1010-1018.
12. Schoener G. Psychotherapist-patient sexual contact after termination of treatment [Letter]. *Am J Psychiatry* 1992;149:981.
13. An Independent Task Force Commissioned by the College of Physicians and Surgeons of Ontario. The Preliminary Report of the Task Force on Sexual Abuse of Patients; 1991 May 27.

ANNOTATED BIBLIOGRAPHY

1. Council on Ethical and Judicial Affairs of the American Medical Association. Sexual misconduct and the practice of medicine. *JAMA* 1991;266:2741-2745.
Thoughtful discussion of the topic, proposing that all sexual contact during the physician-patient relationship is unethical.
2. Gabbard GO, Nadelson C. Professional boundaries in the physician-patient relationship. *JAMA* 1995;273:1445-1449.
Discusses how sexual misconduct with patients usually begins with apparently minor violations of the therapeutic relationship.

Secret Information about Patients

Physicians might receive information about a patient from family members or friends who ask that their role be kept secret (1). Doctors find such unsolicited information disconcerting. Telling the patient the secret might pass on inaccurate or unhelpful information, while keeping the secret might involve the physician in deception. This chapter discusses the ethical issues posed by such secret information and how physicians can respond.

TYPES OF SECRETS

Most commonly, a family member tells the doctor about the patient's deleterious personal habits, such as alcohol use or smoking (1). The family member often tells a member of the physician's staff rather than the physician directly. The informer hopes that the physician will make the patient stop these unhealthy behaviors. Another type of secret involves mental or physical incapacity. The family member might tell the physician that the patient is demented, depressed, or psychotic. Similarly, the family might be concerned that an elderly patient can no longer drive safely or live independently. The confider also might seek to draw the physician into family disputes over money, marital problems, or the lifestyles of grown children. Finally, family members might alert the physician to hidden physical symptoms, such as chest pain, that the patient might choose not to discuss.

PROBLEMS WITH SUCH INFORMATION

Secret information can be problematic in many ways. The information might be inaccurate. The informer might have ulterior motives, such as gaining an advantage in a family dispute. Secrets are disrespectful to the patient because they involve deception rather than open discussions. Finally, such secret disclosures trap the physician in a bind because both disclosing and keeping the secret are objectionable.

APPROACHES TO SECRETS

When presented with such a secret, the physician has several options, some of which involve deception or undermine patient trust.

REVEAL THE SECRET TO THE PATIENT

There are several ethical objections to keeping such a secret. Patients might consider it a violation of trust if physicians talk to other people about them behind their backs (2). Patients might question the physician's allegiance. It is also deceptive for physicians to base their recommendations

and plans on secret information from third parties rather than on the history obtained from the patient. Chapter 6 discusses why deception is ethically problematic for physicians.

Keeping secrets from patients is also impractical. Like all forms of deception, it might require additional, increasingly elaborate deception. Patients might ask why the physician is posing a particular question or ordering a particular test. In that case physicians will have to either reveal the secret information or deceive the patient.

DO NOT DISCLOSE TO THE PATIENT

One physician who was philosophically opposed to keeping such secrets found that in about one half of cases he did not tell the patient (1). First, there may be no point in doing so because the information is obvious or trivial. For example, a family member's report that the patient was a heavy smoker provides no new information if the patient smells of cigarettes. Second, the physician does not disclose the information because it is not relevant to the patient's medical care. For example, few physicians want to get involved in a parent's concerns about a patient's marriage. Third, disclosure might do more harm than good in the short run. Revealing the mother's objections to the patient's marriage might well precipitate or intensify a family argument. Fourth, the physician might intend to tell the patient but find no opportunity to bring it up naturally in the conversation. Physicians must appreciate that the right moment to disclose the secret may never occur.

In some cases the physician promised to keep the secret. The physician was then caught between conflicting obligations to be forthright with patients and to keep promises. Physicians can avoid this dilemma and maintain their primary obligation to the patient by rejecting the informer's initial request to keep the information secret. Family members often preface their revelations with phrases such as, "I don't want my husband to know I told you, but. . . ." It would be prudent for physicians to interrupt at this point, before the information is revealed, and explain their policy of disclosing such information and its source to patients.

ASK INFORMERS TO DISCLOSE THEIR ROLE

Ethically, the best approach is for the physician to convince the informer to tell the patient about the information presented to the physician or to allow the physician to disclose the source of the information. If this is done, the physician can discuss the issue freely with the patient.

In summary, physicians face dilemmas when family members or friends give information about patients that they ask to be kept secret. Acquiescence with such secrets, even if well intentioned, might undermine the patient's trust. Telling the family member or friend that the information needs to be shared with the patient is the most effective way to prevent such an outcome.

REFERENCES

1. Burnham JF. Secrets about patients. *N Engl J Med* 1991;324:1130-1133.
2. Bok S. *Secrets*. New York: Pantheon Books, 1982.

ANNOTATED BIBLIOGRAPHY

1. Burnham JF. Secrets about patients. *N Engl J Med* 1991;324:1130-1133.
Thoughtful discussion of the topic based on the author's clinical experience.

Clinical Research

Clinical research is essential for medical progress. Physicians can be involved in research in various roles, from referring patients to a clinical study to serving as an investigator. In these roles physicians need to understand the ethical issues raised by each stage of clinical research.

ETHICAL ISSUES AT VARIOUS STAGES OF RESEARCH

When patients consider entering a research project, their personal physicians should make a recommendation about participation. Even if an institutional review board (IRB) or a funding agency has approved the project, the treating physician needs to assess independently whether the research study is appropriate for that particular patient. Moreover, when studies target persons with a particular medical condition, many IRBs do not allow researchers to contact participants directly without the treating physician's permission. Among the relevant considerations are the importance of the research question, the rigor of the study design, the selection of participants, and the risks and benefits of the study. Because of the social utility of clinical research, physicians generally should encourage their patients to participate in well-designed studies, but treating physicians also need to protect their patients' interests.

Traditionally, clinical research has been regarded as risky and potential participants were considered guinea pigs who might be subjected to dangerous interventions that would confer little or no benefit and who therefore needed to be protected. Increasingly, however, clinical research is regarded as beneficial rather than risky because it provides access to potentially life-saving new therapies in such conditions as cancer, human immunodeficiency virus (HIV) infection, and organ transplantation. Patients who are eager to obtain promising new drugs for fatal conditions want increased access to clinical research, not greater protection (1).

Clinical research should be distinguished from innovative clinical practice, in which a physician goes beyond the usual standards of practice to try to benefit a particular patient. For example, a surgeon might modify a technique or an internist might use a drug for an indication not approved by the Food and Drug Administration (FDA).

DESIGN OF THE RESEARCH PROTOCOL

According to the ethical guideline of beneficence, research protocols should aim to provide valid and generalizable knowledge and the research's prospective benefits should be proportional to the risks to participants. Thus, if the research question has already been settled or is trivial, or if the design of the study is so weak that valid conclusions are impossible, even slight risk to participants cannot be justified.

Randomized Controlled Trials

Although randomized controlled trials are the most rigorous design for evaluating interventions, they might present special ethical concerns because treatment is determined by chance. The ethical basis for assigning treatment by randomization is the judgment that both arms of the protocol are in clinical equipoise. Current evidence does not prove that either arm is superior. Some experts believe that one arm offers more effective treatment, but others believe the opposite (2). Furthermore, individual patients and their physicians must find randomization acceptable. If physicians believe strongly that one arm of the trial is superior for a particular patient and can provide treatment offered in that arm outside the study, they cannot in good faith recommend that patients enter the trial. Similarly, a particular patient might not consider the alternatives equivalent, as when medical and surgical interventions are compared.

SELECTION OF PARTICIPANTS IN RESEARCH

CASE 28.1 Research on patients with dementia.

A new urinary catheter has been devised. A clinical trial is proposed to evaluate whether the new catheter is clinically more effective than the conventional catheter. Nursing home residents with Alzheimer disease and incontinence will be recruited as participants because enrollment and follow-up will be easier than in ambulatory patients.

Participants in research assume risks in order to gain potential benefits for themselves and for society as a whole. The potential benefits and harms of participation in research should be distributed equitably among groups eligible for the study. Vulnerable, disadvantaged, or minority groups should be neither overrepresented in dangerous studies nor underrepresented in trials of promising new therapies.

Patients Who Lack Decision-making Capacity

As in Case 28.1, patients who lack decision-making capacity cannot give informed consent to research studies, yet research is essential to improve therapies for their conditions. It seems reasonable to allow surrogates to consent to research that presents minimal risks and offers the prospect of direct therapeutic benefits to participants (3). One study cautions, however, that surrogate decisions regarding research for mentally incapacitated persons often are not based on the patients' wishes or best interests (4). In that study 31% of surrogates who believed that the patient would refuse to participate nonetheless gave consent, apparently contradicting the patient's preferences. Furthermore, 20% of surrogates who would not themselves agree to the study nevertheless allowed the patient to participate in the research, perhaps acting in a manner contrary to what they consider the patient's best interests.

Patients Whose Consent Might Not Be Free

Potential participants in research might be vulnerable because their consent might be constrained. Participants might depend on physician-researchers for ongoing medical care, as in nursing homes, Veterans Affairs hospitals, or public hospitals and clinics. As in Case 28.1, such dependent populations are sometimes recruited as research participants because access for recruitment is easier and follow-up more complete than with more autonomous individuals. However, such patients might not feel free to refuse to participate. They or their surrogates might fear that their physicians will be upset if they do not enroll in research studies, in which case they could not readily transfer their care to another physician or institution.

Fairness requires that vulnerable populations not be used as a source of research participants primarily for the convenience of investigators, if other populations would also be suitable participants for the study. The use of vulnerable participants for research is more justifiable if the research addresses the condition that makes the participants vulnerable, if it offers the prospect of direct therapeutic benefit, or if advocates for the vulnerable population have approved the project.

INFORMED CONSENT

The guideline of respect for persons and their autonomy requires that adult participants give informed consent to participate in research. Participants in research should be regarded not as sources of data

but as individuals whose welfare and rights must be respected. The primary physician plays an important ethical and clinical role in helping the patient make an informed decision, as in the following case.

CASE 28.2 Invasive hemodynamic monitoring.

A 70-year-old woman develops congestive heart failure after a myocardial infarction. She is eligible to participate in a study of the dose-response properties of a new angiotensin-converting enzyme inhibitor in patients with congestive heart failure. The study involves Swan-Ganz catheterization and hemodynamic monitoring in the coronary care unit when the drug is started and again 6 months later. The patient has always been reluctant to be hospitalized and to undergo invasive cardiac procedures.

In this case participation in the study offers little direct benefit to the patient. Numerous effective standard therapies exist. Although patients generally should be encouraged to enter well-designed clinical studies for altruistic motives, this patient might well react adversely to a prolonged stay in intensive care or to invasive procedures. The primary physician should raise these concerns with the patient and try to ensure that the patient is informed about the research study. Table 28-1 lists pertinent issues that the prospective subject needs to understand (5).

The Nature of the Research Project

The prospective subject should be told explicitly that research is being conducted, what its purpose is, and how the participants are being recruited. Any financial interest of the investigators in the drug or device being studied needs to be disclosed (6).

The Procedures of the Study

Participants need to know what they will be asked to do in the research project. On a practical level, they should be told how much time will be required and how often. That blood will be drawn might mean more to participants than the names of the tests that will be conducted. Procedures that are not standard care should be identified as such. Alternative procedures or treatments that might be available outside the study should be discussed. If the study involves blinding or randomization, these concepts should be explained in terms that the patient can understand.

The Potential Harms and Benefits of the Study

Medical, psychosocial, and economic harms and benefits should be described in lay terms. These include physical harm from complications of tests or treatments, as well as psychosocial harm such as loss of privacy and inconvenience.

Economic risks might also be important. Participants should appreciate that insurance companies may deny reimbursement for procedures that are not standard clinical care. In Case 28.2, for example, the patient needs to understand that she might need to pay for the costs of hemodynamic monitoring in the cardiac care unit, which would not ordinarily be carried out.

Assurances That Participation in the Research Is Voluntary

Participants must be told that declining to participate in the study will not compromise their medical care and that they may withdraw from the project at any time.

TABLE 28-1

Informed Consent in Research Projects

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Misconceptions About Research

A common misconception is that research will provide direct therapeutic benefits to the participants. This has been termed the *therapeutic misconception* (7,8). Most promising new interventions, despite encouraging preliminary results, fail to show significant advantages over standard therapy. Patients might downplay the risks and be unrealistically optimistic about the benefits.

The primary physician plays a crucial role in helping the patient make an informed decision. After talking with an enthusiastic clinical investigator, patients might have an unrealistic impression of the study. The primary physician can elicit and correct any misunderstandings and encourage the patient to ask questions. Finally, the primary doctor should make a recommendation on the basis of the patient's values. In Case 28.2, given the patient's reluctance about invasive procedures, the physician should recommend against participating in the protocol.

PROTECTION OF CONFIDENTIALITY

Confidentiality is important for its own sake (see Chapter 5) and also promotes participation in research. For example, concerns about breaches of confidentiality might deter potential participants from participating in research regarding HIV infection, mental illness, or genetics. Investigators need to take appropriate steps to protect the confidentiality of research data. During the informed consent process, potential participants need to be told about possible risks to confidentiality and the steps that will be taken to avoid them.

In some studies identification of child abuse, elder abuse, or contagious diseases can be anticipated. In clinical practice such cases must be reported to appropriate officials. Investigators need to determine in advance whether cases identified during the research project will be reported and, if so, inform patients during the informed consent process.

REVIEW BY AN INSTITUTIONAL REVIEW BOARD

Approval from an IRB is required for most federally funded research, for research that will be submitted to the FDA to gain approval for new therapies, and for all researchers at many universities. The function of IRB review is to protect research participants. The best-intentioned researchers, in their eagerness to conduct important research, might not pay sufficient attention to potential ethical problems.

COMPETING AND CONFLICTING INTERESTS

The researchers and the treating physicians might have competing and conflicting interests because the goal of carrying out important and valid research might conflict with the goal of acting in the best interests of the individual patient.

COMPETING AND CONFLICTING INTERESTS FOR TREATING PHYSICIANS

Finder's Fees for Research Participants

In some situations physicians might receive a finder's fee for referring patients to a research project.

CASE 28.3 Finder's fees.

To encourage enrollment in a clinical trial of a new antibiotic, physicians are offered \$350 for referring patients who subsequently enroll in the study. The referring physician needs to make a phone call to the coordinating research nurse, who will explain the study to the patient.

Enrollment is often the rate-limiting step in clinical trials, and finder's fees facilitate their completion. However, finder's fees also give the appearance that physicians refer patients to clinical trials for their own interest rather than the patient's (9). Critics of finder's fees also point out that the analogous situation of kickbacks for referring patients to another physician for clinical care is considered unethical. Furthermore, the physician's reward might seem excessive for the services rendered.

Dual Roles for Clinician-Investigators

The investigator might also be an eligible research subject's primary physician. Such patients might fear that their future care will be jeopardized if they decline to participate in research. Furthermore, what is best for a particular patient's medical care might not be what is best for the research project. In some situations it might be better for the patient to drop out of the study and receive individualized care that differs from the research protocol. As an investigator, however, the physician wants study participants to continue to the end of the trial. If many participants drop out, the study's capacity to answer the research question will be compromised.

Such role conflicts should be explained to participants in advance. Whenever possible, the patient should have the opportunity to receive care from a personal physician who is not associated with the study. Because the welfare of the patient should be paramount, the role of personal physician should take priority over the role of clinical researcher.

COMPETING AND CONFLICTING INTERESTS FOR RESEARCHERS

Physician-researchers might have competing or conflicting interests that might compromise their research's integrity. These other interests might impair researchers' objectivity and undermine public trust in research (10). Even the most scrupulous and well-intentioned investigators might subconsciously introduce bias into the research design, data collection, or analysis (10,11).

Academic Rewards

Research publications lead to academic prestige, grants, and promotions.

Research Funded by Drug Manufacturers

Clinical investigators are increasingly turning to drug companies for funding (12). The company manufacturing the drug has an interest in having the drug proved effective. Thus, the bias against publishing negative studies might be particularly strong in studies sponsored by drug companies (13). Another problem is that reimbursement from the drug company to investigators might greatly exceed the research's actual costs. Such excess reimbursement might offer researchers perverse incentives both to suggest experimental therapy for a patient when conventional therapy is in the patient's best interests and to interpret findings in the most favorable light (14).

Financial Interest in the Drug Manufacturer

Investigators might hold stock or stock options in the company making the drug under study, thus making their compensation affected by the study's results. Clinical researchers who hold options might reap huge financial rewards if the treatment were shown to be effective, in addition to any compensation for time and effort. However, if the drug proves ineffective, investigators face an inevitable conflict of interest: Fostering scientific progress will unavoidably harm their personal financial interests.

RESPONDING TO COMPETING AND CONFLICTING INTERESTS

Treating physicians must respond to competing and conflicting interests regarding research they conduct or refer patients to. This chapter will not discuss how researchers should address conflicts of interest in their role (5,15).

Disclose Competing and Conflicting Interests

Treating physicians need to disclose to patients if they are also investigators in any research projects that they discuss with the patient or to which they refer the patient. In a landmark court case a patient sued a physician-researcher who had patented a cell line derived from the patient's cells without his knowledge or permission (6). The patient alleged that the physician-researcher had failed to disclose his personal financial stake in the research and had recommended several procedures without disclosing that they were for research, not clinical care. The California Supreme Court declared that physicians need to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment (6)." This ruling implies that patients must be told if referring physicians receive a finder's fee for referring patients to a study.

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Manage Competing or Conflicting Interests

Although disclosure is necessary to protect patients, in some situations treating physicians need to go further and manage or eliminate conflicts of interest. Problems with finder's fees can be eliminated if the amount of the fee is commensurate with the services performed. If a physician is simply making a phone call to refer the patient, \$350, as in Case 28.3, seems excessive.

If the treating physician is also an investigator in a clinical trial the patient enrolls in, whenever possible the patient should be offered the opportunity to receive care from a personal physician who is not associated with the study. Because the patient's welfare should be paramount, the personal physician's role should take priority over the clinical researcher's role.

Ban Certain Situations That Give Rise to Conflicts of Interest

Clinical investigators should avoid direct financial stakes in the therapies under evaluation. As one writer has noted, "It is difficult enough for the most conscientious researchers to be totally unbiased about their own work, but when an investigator has an economic interest in the outcome of the work, objectivity is even more difficult (10)." Many productive investigators support such prohibitions (16,17).

In conclusion, rigorous clinical research is essential to evaluate promising new therapies. Physicians should encourage patients to participate in appropriate clinical research. Investigators should ensure that the potential benefits of research are proportionate to the risks and that participants give informed consent. Conflicts of interest, which might impair objectivity and erode public trust in research, should be avoided.

REFERENCES

1. Levine C, Dubler NN, Levine RJ. Building a new consensus: ethical principles and policies for clinical research on HIV/AIDS. *IRB* 1991;13:1-17.
2. Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med* 1987;317:141-145.
3. National Bioethics Advisory Commission. *Research involving persons with mental disorders that may affect decision making capacity*. Rockville, MD: National Bioethics Advisory Commission, 1998.
4. Warren JW, Sobal J, Denney JH, et al. Informed consent by proxy: an issue in research with elderly patients. *N Engl J Med* 1986;315:1125-1128.
5. Lo B. Addressing ethical issues. In: Hulley S, Cummings SB, Browner WS, Grady D, Hearst N, Newman TB, eds. *Designing clinical research*, 2nd ed. Philadelphia: Lippincott Williams & Wilkins, 2001:215-230.
6. Moore v. Regents of University of California. 51 Cal.3d 120; Cal. Rptr. 146, 793 P.2d 479 (1990).
7. Lidz CW, Appelbaum PS. The therapeutic misconception: problems and solutions. *Med Care* 2002;40(9 Suppl): V55-V63.
8. Joffe S, Cook EF, Cleary PD, et al. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet* 2001;358(9295):1772-1777.
9. Lind S. Finder's fees for research subjects. *N Engl J Med* 1990;323(3):192-194.
10. Relman AS. Economic incentives in clinical investigation. *N Engl J Med* 1989;320:933-934.
11. Hillman AL, Eisenberg JM, Pauly MV, et al. Avoiding bias in the conduct and reporting of cost-effectiveness research sponsored by pharmaceutical companies. *N Engl J Med* 1991;324:1362-1365.
12. American Federation for Clinical Research guidelines for avoiding conflict of interest. *Clin Res* 1990;38:239-240.
13. Davidson DA. Source of funding and outcome of clinical trials. *J Gen Intern Med* 1986;1:155-158.
14. Shimm DS, Spece RG. Industry reimbursement for entering patients into clinical trials: ethical issues. *Ann Intern Med* 1991;115:148-151.
15. Lo B, Wolf LE, Berkeley A. Conflict-of-interest policies for investigators in clinical trials. *N Engl J Med* 2000; 343:1616-1620.
16. Healy B, Campeau L, Gray R, et al. Conflict-of-interest guidelines for a multicenter clinical trial of treatment after coronary-artery bypass-graft surgery. *N Engl J Med* 1989;320(14):949-951.
17. Topol EJ, Armstrong P, Van de Werf F, et al. Confronting the issues of patient safety and investigator conflict of interest in an international trial of myocardial reperfusion. *J Am Coll Cardiol* 1992;19:1123-1128.

ANNOTATED BIBLIOGRAPHY

1. Levine RJ. *Ethics and regulation of clinical research*. Baltimore, MD: Urban & Schwarzenberg, 1986. Comprehensive and thoughtful book on all aspects of designing and conducting clinical research.
2. National Bioethics Advisory Commission. *Research involving persons with mental disorders that may affect decisionmaking capacity*. Rockville, MD: National Bioethics Advisory Commission, 1998. Analyzes ethical dilemmas that occur when research participants lack the capacity to make informed decisions.
3. Federman DD, Hanna KE, Rodriguez LL, eds. *Responsible research: a systems approach to protecting research participants*. Washington: National Academies Press, 2003.

Comprehensive report from the Institute of Medicine on the oversight of research with human participants, discussing how to improve the IRB system.

4. Field MJ, Behrman RE, eds. *The ethical conduct of clinical research involving children*. Washington: National Academies Press, 2004.

Report from the Institute of Medicine on the special ethical issues concerning research with children.

5. Lidz CW, Appelbaum PS. The therapeutic misconception: problems and solutions. *Med Care* 2002;40(9 Suppl): V55–V63.

Explains that research subjects commonly believe that research is designed to provide them therapeutic benefits, when in fact the goal of research is to advance scientific knowledge.

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SECTION V

Conflicts of Interest

Overview of Conflicts of Interest

In *The Doctor's Dilemma*, George Bernard Shaw questioned whether people can be “impartial where they have a strong pecuniary interest on one side (1).” He wrote, “Nobody supposes that doctors are less virtuous than judges; but a judge whose salary and reputation depended on whether the verdict was for plaintiff or defendant, prosecutor or prisoner, should be as little trusted as a general in the pay of the enemy. To offer me a doctor as my judge, and then weight his decision with a bribe of a large sum of money . . . is to go wildly beyond . . . [what] human nature will bear (1).” Shaw’s words have particular relevance to contemporary U.S. medicine because of increasing concerns over conflicts of interest.

A conflict of interest exists when a person entrusted with the interests of a client, dependent, or the public violates that trust. Rather than acting in the patient’s best interests, physicians might promote their own self-interest or the interests of a third party, such as a hospital, physician group, or insurance plan. Some conflicts of interest are financial, such as those resulting from reimbursement incentives or personal investments in medical facilities. Other conflicts of interest involve personal or professional roles, as when physicians respond to mistakes, deal with impaired colleagues, or need to learn invasive procedures.

Conflicts of interest might be ethically problematic for physicians for several reasons. First, patients might suffer physical harm. Second, even though the patient suffers no clinical harm, the integrity of medical judgment might be compromised. Third, conflicts of interest undercut patients’ trust that physicians are acting on their behalf.

Chapters 30 to 36 analyze specific conflicts of interest. This chapter discusses how to define conflicts of interest, who should decide what constitutes an unacceptable conflict of interest, and how physicians can manage conflicts of interest.

CONFLICTS OF INTEREST IN NONMEDICAL SITUATIONS

Conflicts of interest occur in all professions and in public service (2). For example, a trustee might use the trust fund of an elderly person or child for his own profit. A public official might accept expensive gifts or trips from a company whose business he or she oversees.

Consider a judge who presides over a case involving a relative or a former law partner or in which the judge has a personal financial stake in the outcome (3). In such a situation the judge’s decisions might favor the relative, the former partner, or self-interest. Even if the outcome of the legal proceedings is fair, the process by which the decision was reached might be biased. For instance, the judge might take into account inappropriate factors or make rulings about motions and objections that no impartial decision-maker would make. These procedural errors would be disturbing even if the outcome seemed fair. Public trust in the judicial system might be undermined. Simply the appearance of a conflict of interest might be unacceptable.

The judge might honestly believe that he or she will be impartial and might even consciously try to compensate for having ties to a litigant. Nonetheless, the opposing party and the public might still suspect that another judge would have decided the case differently. People naturally tend to believe that they are acting with integrity, even when this might not be the case. Thus, even if the individual judge believes that he or she can be impartial, that judge might be required to withdraw from the case. Society decides when judges or officials must recuse themselves, through legislation, regulation, and case law (3). There is no implication that the judge is immoral or unprofessional. Instead, the idea is that it would be untenable to place anyone in such a situation.

HOW ARE CONFLICTS OF INTEREST DEFINED?

People often use the term "conflict of interest" without defining it clearly.

DETRIMENTAL PATIENT OUTCOMES

In medicine, the narrowest definition of conflict of interest is that the patient's outcome is worse because the physician has subordinated the patient's best interests (4,5). The physician might do so either intentionally or subconsciously.

COMPROMISE OF PHYSICIANS' JUDGMENT OR THE DECISION-MAKING PROCESS

More broadly, the physician's judgment or decision-making process might be compromised, even though clinical outcomes are not impaired. Failure to order an indicated test or therapy because of a conflict of interest must be distinguished from an error or incompetence.

POTENTIAL FOR DETRIMENTAL OUTCOMES OR COMPROMISED JUDGMENT

A still broader definition of conflicts of interest includes the *potential* for detrimental outcomes or for compromised judgment without evidence of *actual* harm or compromised judgment (6). For example, personal investments in medical facilities provide physicians financial incentives for ordering more services, even when they are not medically necessary (see Chapter 31). In any particular case, however, it might be difficult to show that a physician's decisions are inappropriate or that the patient suffered harm.

PERCEIVED CONFLICTS OF INTEREST

Some situations present only *perceived* conflicts of interest, without actual harm or even significant potential for harm. For example, many physicians believe that accepting small gifts from drug companies, such as pens and writing pads, is harmless (see Chapter 33), but the perception of a conflict of interest might be damaging even though the actual or potential harm to patients is small. If the public believes that physicians are serving the interests of drug companies rather than those of their patients, trust in the individual doctor or the profession as a whole might be undermined.

Physicians might be offended because concerns about potential or perceived conflicts of interest seem to impugn their integrity. Doctors need to understand that the public is not singling them out for censure, but simply treating them as human and therefore fallible. The situation is problematic, not the person; it would be untenable to place anyone in such a situation.

COMPETING VERSUS CONFLICTING INTERESTS

The interests of the patient and physician never coincide completely. *Conflicting* interests cannot both be fulfilled. The physician literally cannot advance one interest without setting back the other. *Competing* interests, in contrast, though not congruent with the patient's best interests, can be furthered without harm to the patient. Conversely, the patient's interests can be achieved without gravely setting back the competing interests. For example, time devoted to patient care cannot be spent on continuing medical education, teaching, clinical research, personal hobbies, or family activities. Such competing interests can usually be accommodated.

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SITUATIONS THAT ARE NOT CONFLICTS OF INTEREST

The term *conflict of interest* is often used loosely. A conflict of interest, in the senses defined above, needs to be distinguished from conflicts between ethical guidelines, disagreements among health care professionals, or disagreements between patients and physicians.

REIMBURSEMENT INCENTIVES

Medicine is regarded as an altruistic profession because its primary goal is to benefit the patient, not to maximize physicians' income. However, no one expects physicians to work for free or begrudges them a comfortable income. Helping the sick is commendable and difficult work and requires extensive training. This tension between altruism and self-interest is unavoidable in medicine (7). Financial rewards to the doctor should ideally be secondary to fostering patients' well-being.

Any reimbursement system might provide incentives to physicians to act contrary to patients' best interests. Fee-for-service reimbursement provides incentives to increase services and to give services of little or no benefit, thereby raising the cost of health care (see Chapter 31). Managed care systems, which use capitation and prospective payment, might provide incentives to decrease health care services and withhold beneficial care (see Chapter 32).

The concern about financial incentives is not simply that unscrupulous physicians will deliberately subordinate the patient's interests to their own self-interest or the interests of hospitals or insurance plans (8). Subtle incentives might also exert unconscious influence on physician decisions. When several management options are plausible, "financial incentives may influence even the best, most highly principled doctors to overlook subtle clues that suggest an optimal approach (8)."

MANAGING CONFLICTS OF INTEREST

It is often difficult to draw a clear line between improper conflicts of interest and situations in which the interests of the patient are adequately protected. When conflicting interests are identified, how can sick and vulnerable patients be protected? Physicians should take the following steps (Table 29-1), which are discussed in more detail in subsequent chapters dealing with specific conflicts of interest.

REAFFIRM THAT THE PATIENT'S INTERESTS ARE PARAMOUNT

Individual physicians and the medical profession need to reaffirm their fiduciary responsibility to their patients (9). The doctor's primary responsibility is to foster the well-being of patients, not the doctor's own self-interest or third parties' interests.

To check whether they are acting in the patient's best interest, doctors might ask what they would recommend if they were working under the opposite reimbursement system. Physicians in managed care might ask whether they would recommend the intervention under fee-for-service. Similarly, fee-for-service physicians might ask what they would recommend if they or the hospital would lose money doing the procedure. The answer is simple: Physicians should recommend care that is in the patient's best interests, no more and no less. The goal of economic incentives should be to "prompt the physician to consider costs appropriately—to remind him pointedly that economics really does matter—but not to distort his reasoning. A well-designed incentive should prompt the physician to

TABLE 29-1

Managing Conflicts of Interest

- Reaffirm that the patient's interests are paramount.
- Disclose conflicts of interest.
- Take precautions to protect patients.
- Prohibit certain actions and situations.

consider more carefully what he does with clinical uncertainties and borderline options; it should not induce him to forego what he believes is clearly in the patient's interest (10)."

Although reaffirming fiduciary responsibilities to the patient is a necessary first step, other steps might also be needed.

DISCLOSE CONFLICTS OF INTEREST

Disclosure is salutary for several reasons. First, the requirement to disclose incentives might prevent physicians and organizations from making unacceptable arrangements. If the physician would find it hard or awkward to justify a situation, it probably presents an unacceptable conflict of interest. In controversial situations it is prudent for physicians to err on the side of the patient's interests rather than their own self-interest. Second, patients who know about a conflict of interest might be able to make more informed decisions by placing the physician's recommendations in context and compensating for any bias. However, it might be unrealistic to expect patients to assess whether a situation has biased the physician's judgment. Thus, in many situations, disclosure alone might be inadequate to protect patients.

TAKE PRECAUTIONS TO PROTECT PATIENTS

In some circumstances society may determine that additional steps must be taken to safeguard patients or the public. Physicians' actions may be regulated and their discretion limited (11). For example, in clinical research, review by an institutional review board is required (see Chapter 28).

PROHIBIT CERTAIN ACTIONS AND SITUATIONS

Although disclosure and precautions are necessary steps, they might still be insufficient to protect patients. Some actions and situations present such strong and direct conflicts of interest that they should be prohibited. Because "it is difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not," it might be prudent to prohibit certain actions and situations (6). For example, continuing education programs controlled by drug companies might provide biased or incomplete coverage of topics. To avoid this, programs should not accept support from drug companies that attempt to influence the choice of topics or speakers (see Chapter 33).

In summary, conflicts of interest are ethically perilous because they might harm patients, impair physician judgment, and undermine trust in physicians. The ethical ideal is that patients' interests should take priority over physicians' self-interest or third parties' interests.

REFERENCES

1. Shaw GB. *The doctor's dilemma*. London: Penguin Books, 1946.
2. Wells P, Jones H, Davis M. *Conflicts of interest in engineering*. Dubuque: Kendall/Hunt Publishing Company, 1986.
3. Gillers S, Dorsen N. *Regulation of lawyers: problems of law and ethics*. Boston: Little, Brown and Company, 1989:790-808.
4. Rothman KJ. Conflicts of interest: the new McCarthyism in science. *JAMA* 1993;269:2782-2784.
5. Rodwin MA. *Medicine, money, and morals: physicians' conflicts of interest*. New York: Oxford University Press, 1993.
6. Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993;329:573-576.
7. Jonsen AR. Watching the doctor. *N Engl J Med* 1983;308:1531-1535.
8. Hillman AL. Health maintenance organizations, financial incentives, and physicians' judgments. *Ann Intern Med* 1990;112:891-893.
9. Medical professionalism in the new millennium: a physician charter. *Ann Intern Med* 2002;136(3):243-246.
10. Morreim EH. *Balancing act: the new medical ethics of medicine's new economics*. Boston: Kluwer Academic Publishers, 1991:124.
11. Rodwin MA. *Medicine, money, and morals: physicians' conflicts of interest*. New York: Oxford University Press, 1993:179-211.

Bedside Rationing of Health Care

Physicians are ethically obligated to act in patients' best interests (*see* Chapter 4). However, acting in the best interests of one patient might sometimes make it impossible for physicians to act on behalf of another patient who is much more likely to benefit from care. Dilemmas arise because resources such as physician time and intensive care beds are in limited supply and people have different priorities for limited resources (1,2).

CASE 30.1 Limited coronary care beds.

Mr. H presents to the emergency department with substernal chest pain. An electrocardiogram (ECG) shows an acute anterior myocardial infarction, multifocal ventricular premature beats, and some couplets. The cardiac care unit (CCU) and intensive care unit (ICU) are full. One of the patients in the CCU is a 73-year-old man who had an emergency operation for a ruptured aortic aneurysm. A week after the operation, he is comatose, septic, in ventilatory and renal failure, and has hypotension despite vasopressors. Another patient in the CCU experienced chest pain after an angioplasty earlier in the day but has no persistent ECG changes and has normal cardiac enzymes. The physicians consider whether to transfer one of these patients out of the CCU to free a bed for Mr. H.

In Case 30.1 the patient with multisystem failure is so sick that he is highly unlikely to survive even if CCU care is continued. The postangioplasty patient is receiving only monitoring, not active treatment, and is highly likely to have a good outcome even if he is transferred out of the unit. In contrast, Mr. H might benefit greatly from thrombolytic and antiarrhythmic therapy, which can be administered only in an ICU. If CCU beds were allocated on a strictly first-come, first-served basis, Mr. H would be denied substantial benefits.

This chapter discusses the ethical considerations that arise when one patient's interests conflict with other patients' interests. In addition, this chapter analyzes whether the scarcity of financial resources justifies limiting the care of an individual patient. Chapter 34 deals with conflicts of interest between the health care provider and patient rather than conflicts of interest between patients.

The terms used to discuss these issues are hard to define precisely, are often used inconsistently, and commonly evoke strong emotions (3–5). In this book "allocation" refers to decisions that set levels of funding for programs rather than determine care for individual patients. For example, funds must be allocated between Medicaid and other social programs such as education and transportation and, within Medicaid, between inpatient services and prenatal care. Sometimes these policy-level choices are termed "macroallocation." In contrast, this book uses the term "rationing" to refer to decisions at the bedside or in the office to limit care for individual patients because of limited resources. The term *rationing* often connotes limiting beneficial care because it is too expensive. The term "microallocation" is also used in this context. The term rationing excludes

clinical decisions that are a straightforward implementation of macroallocation policies, such as health plans' decisions not to cover cosmetic surgery. Unlike other countries, such as Great Britain, the United States has not developed coherent societal allocation policies (6,7). The ethical issue is whether, in the absence of a fair social agreement on allocation, physicians can ethically carry out rationing at the bedside.

ARGUMENTS AGAINST BEDSIDE RATIONING

Traditionally, bedside rationing by physicians has been considered unethical (8,9). Opponents of bedside rationing argue that doctors should act as fiduciaries and patient advocates, helping patients receive all the beneficial care that the system allows. One eminent physician wrote, "Physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations. In caring for an individual patient, the doctor must act solely as the patient's advocate, against the apparent interests of society as a whole (10)." This fiduciary role is deemed essential for maintaining patient trust. In their roles as citizens and civic leaders, physicians should help determine how resources should be allocated. At the bedside, however, physicians should not limit care to one patient primarily to benefit other patients or to save money for society. Such arguments have particular relevance in for-profit managed care systems in which savings from rationing may be used for executive salaries and returns to shareholders.

ARGUMENTS IN FAVOR OF BEDSIDE RATIONING

An absolute prohibition against bedside rationing, however, is ethically problematic (Table 30-1).

ACTING IN THE PATIENT'S BEST INTERESTS IS NOT AN ABSOLUTE DUTY

The physician's ethical obligation to act in an individual patient's best interests is not absolute. In several circumstances physicians are ethically or legally required to act against the patient's best interests in order to benefit third parties. For example, although maintaining confidentiality of medical information is in a patient's best interest, it is overridden when infectious diseases, threats of physical violence, or the patient's inability to drive safely might harm third parties (*see* Chapter 5). Furthermore, the guideline of beneficence is limited. The physician is not obliged to do literally everything that might benefit the patient. One philosopher writes that the traditional ethic of advocacy needs to be redefined to "proportional advocacy": the advocate "argues not for 'everything possible' but for everything 'probably beneficial' (11)." Similarly, the American Medical Association declares that "physicians must advocate for any care they believe will materially benefit their patients (12)." Other advocates of the fiduciary role enjoin physicians to practise "parsimonious" or "efficient" medicine, without defining those terms (8,9). These views acknowledge that if physicians ordered all tests and drugs that provided any benefit, costs would soar out of control. All these views allow some forms of rationing, without calling it such. It is more honest to call rationing by name (5) and to proceed to more constructive debates over when it is justified (4).

TABLE 30-1

Arguments in Favor of Bedside Rationing

Acting in the patient's best interests is not an absolute duty.
Leaving physicians out of microallocation decisions will harm patients.
Other patients might be seriously harmed if resources are not rationed.

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LEAVING PHYSICIANS OUT OF MICROALLOCATION DECISIONS WOULD HARM PATIENTS

If physicians were not involved in microallocation, clinical decisions would be made according to utilization review guidelines or by health care administrators. Such decisions fail to take into account meaningful differences in individual patient circumstances that are too complex to be captured in simple guidelines or rules (13–16). Physicians can often bring to bear pertinent clinical information to justify an exception to a general rule (17).

OTHER PATIENTS MIGHT BE SERIOUSLY HARMED IF RESOURCES ARE NOT RATIONED

Providing care to one patient might deny care to another patient who would receive much greater medical benefit. Two patients might be competing for such limited resources as physician time or ICU beds. In this situation informal rationing is standard medical practice that has strong ethical justification.

CASE 30.2 Limited physician time.

Mr. M, a 48-year-old man, comes to the physician's office after 40 minutes of crushing substernal chest pain and shortness of breath. At the same time, a 21-year-old woman with asthma comes to the office with worsening shortness of breath for the past day despite increasing use of inhaled bronchodilators. These patients do not have appointments, and the physician's schedule is already full.

Because their time is limited, physicians must decide which patients deserve higher priority. In a life-threatening situation such as a probable myocardial infarction in Case 30.2, the priority of the emergency case over other patients is clear. Mr. M needs to be stabilized and transported to the emergency department. Regularly scheduled patients presumably would agree to wait because they would want similar priority if they should find themselves in such a serious emergency. However, how is an emergency defined? If care is promptly instituted for the woman with a severe asthma attack, her symptoms of shortness of breath will be relieved more rapidly and a hospitalization might be avoided. However, it might be difficult to determine how much benefit or potential harm to the asthma patient justifies asking regularly scheduled patients to wait. Referring the asthma patient to the emergency department would not resolve the dilemma but only push it back a step. Emergency physicians there would need to prioritize patients presenting for care.

Physicians routinely make decisions to allocate their time, and indeed patients and society expect them to do so. It is difficult to imagine that anyone other than the physician or nurse would decide who should wait. General rules can be set—for example, patients with serious emergencies should take priority and patients with minor or self-limited illnesses should wait. However, physicians need to interpret those general rules in a particular case—for example, by deciding whether a patient's asthma attack is severe enough to warrant asking other patients to wait.

In Case 30.1 essential medical resources—CCU beds—are in short supply. Some ethicists assert that physicians have an ethical obligation to ration scarce intensive care beds by transferring out of the CCU patients who are either too sick or too healthy to benefit significantly from intensive care (18). In clinical practice physicians frequently transfer patients in order to allow others to receive intensive care. When the CCU or ICU is full, physicians identify patients who are too sick to benefit from continued intensive care and set more restrictive standards for admission to the unit. Such transfers occur commonly and, under mild resource constraints, physicians can make such transfers without adversely affecting overall patient outcomes (19).

Increasing the supply of CCU beds will not resolve the problem of rationing but only postpone the dilemma of the last bed. Transferring patients to other hospitals with open CCU beds is also not a solution because Mr. H needs immediate treatment.

In Case 30.1 an identified patient would be seriously harmed if care were not rationed. In the following case a future patient will predictably be harmed unless care is rationed.

CASE 30.3 Shortage of blood products.

A 36-year-old man with alcoholic cirrhosis is admitted for severe variceal bleeding and encephalopathy. He is not a candidate for liver transplantation because of his active alcohol and amphetamine use. The surgeons do not believe he will survive a portacaval shunt operation. After 3 days he has consumed 42 units of blood and continues to bleed briskly despite endoscopic sclerotherapy and percutaneous placement of a therapeutic portal-systemic shunt (TIPS). The regional blood bank has only three more units of his type of blood despite appeals for more donations. It is New Year's Eve, when many persons who have met with automobile accidents will need blood transfusions.

In Case 30.3 there is no identified individual who will be harmed if blood products are not rationed, but the existence of such an individual is virtually certain. Many persons with trauma can recover completely with vigorous emergency care. Thus, a future patient might be seriously harmed if all available blood were given to the patient in Case 30.3, who has not improved despite maximal care.

Physicians might be reluctant to ration interventions to patients who are already receiving care because of loyalty or fidelity—that is, doctors might believe that they have implicitly promised to provide ongoing care and not to curtail it to benefit other patients. The position's emotional appeal is clear, and keeping promises is an important ethical guideline. However, maintaining fidelity should refer to appropriate ongoing care, not to unlimited care regardless of the benefits to the patient or the harms to others.

Although limitations on transfusions are justified in Case 30.3, there are problems in implementing such limits in a fair manner. Various physicians might set different limits in practice. Some physicians might stop after 40 units, others after 60 units. More specific practice standards would make such decisions more consistent and therefore fairer.

RATIONING ON THE BASIS OF FINANCIAL RESOURCES

In some situations compelling ethical arguments exist for limiting care to one patient in order to provide much more beneficial clinical services to other patients. However, when rationing is done primarily to save money rather than to benefit other patients directly, the reasons are generally weaker. The following case illustrates these issues.

CASE 30.4 Expensive care for a patient with poor prognosis and quality of life.

Mrs. D is a 76-year-old woman with severe dementia. She recognizes her family only occasionally and does not respond to health care workers' questions or requests. She develops chronic renal failure and symptoms of uremia. While competent, she had never expressed her preferences about renal dialysis. Although her primary physician and the nephrologist strongly recommend that renal dialysis not be performed, her family insists on it. They believe that as long as she recognizes them and smiles, her life should be prolonged. They understand that dialysis would not improve her mental functioning or mobility.

At the time the public hospital in the community is considering closing obstetrical and substance abuse services because of budget deficits. The physicians feel they are accomplices to an unjust health care system if they use resources on this patient when more pressing health needs are unmet. A vascular surgery consultant writes in the medical record, "In the current climate of out-of-control medical costs, it is unconscionable to provide expensive care for this patient."

As discussed in Chapter 14, it would be appropriate to provide renal dialysis to Mrs. D because it would achieve the family's goal of prolonging her life at a quality they consider acceptable. The physicians, however, believe that Mrs. D's quality of life is so poor that the cost of dialysis is not justified.

Physicians should support more enlightened policies regarding allocation, but in most circumstances attempts by physicians to ration care on the basis of costs at the level of the individual patient, although well intentioned, are not justified.

NO PUBLIC POLICY AUTHORIZES PHYSICIANS TO RATION ON THE BASIS OF COSTS

The physicians caring for Mrs. D felt partly responsible for the soaring cost of health care. However, no public policy authorizes physicians to limit the care of patients on renal dialysis to save resources for other patients. On the contrary, U.S. public policy pays for dialysis to all patients

with end-stage renal failure. In the 1960s selecting patients for a limited number of renal dialysis machines on the basis of prognosis or quality of life proved so controversial that Congress singled out end-stage renal disease for universal coverage under the Medicare program.

BEDSIDE RATIONING BASED ON COSTS WOULD BE INCONSISTENT AND UNFAIR

Physicians at one hospital might withhold dialysis from Mrs. D, but physicians at another hospital might provide it. Indeed, the public nursing home in the area provided chronic dialysis to numerous patients with severe Alzheimer's disease. It violates the ethical guideline of justice to treat similar patients unequally. Whether or not Mrs. D receives dialysis should not be based on the choice of hospital.

Bedside rationing might also be unfair if certain patients or certain interventions are singled out for review. It makes little sense to limit one health care intervention as not cost-effective without looking at the cost-effectiveness of other interventions as well. Many people would object to limiting dialysis for Mrs. D if other interventions, such as intensive care for patients with extremely poor prognoses, were not similarly scrutinized.

MONEY SAVED BY RATIONING CANNOT BE REALLOCATED

Physicians in the United States who save money on the care of an individual patient generally cannot redirect those resources to patients or projects with higher priority (20). If physicians terminated dialysis on Mrs. D, they could not redirect funds to more pressing medical or social needs, such as prenatal care or childhood immunizations. Furthermore, in managed care organizations savings from limiting care to patients might be directed toward higher salaries for administrators or greater profits for investors (21). In the absence of broader health care reform, attempts to limit health care costs at the bedside are ineffective gestures.

Limiting care for one patient in order to have resources available to patients who would benefit more from them is more strongly justified if several conditions are met (22). First, saved resources would be reallocated to interventions that provide greater benefits for the population of patients receiving care. Second, the physicians would not benefit directly from saving resources. Third, the limitations in care are applied to all similar patients with no exceptions based on privileged social status.

Opponents of bedside rationing would argue that physicians in Case 30.4 fulfilled their ethical obligations to use limited resources prudently by discussing dialysis with Mrs. D's family and making a strong recommendation against it.

AN EXAMPLE OF ETHICALLY ACCEPTABLE BEDSIDE RATIONING: TIERED FORMULARY BENEFITS

In some situations it is ethically acceptable for physicians to limit services to one patient in order to conserve a pool of money that pays for services to a population of patients. Formulary restrictions are one common example. Because drug expenditures are the fastest growing of all health care costs, most managed care plans have established restricted formularies and tiered copayments. For example, patients might have a \$10 copayment for preferred drugs on the formulary, a \$20 copayment for nonpreferred formulary drugs, and a still higher copayment for nonformulary drugs. Preferred drugs are usually cheaper than other drugs in the same class because a discount from the manufacturer has been negotiated.

In some situations there might be no meaningful clinical differences among drugs in a class but significant differences in cost—for example, different angiotensin converting-enzyme inhibitors for congestive heart failure. It is ethical for the physician to start with the presumption that preferred formulary drugs are appropriate. For instance, the physician can recommend that the patient try a preferred drug. For a stable chronic condition, the risk to the patient of using a preferred medication within the same class of drugs is small, provided the patient receives close follow-up care.

This presumption in favor of a preferred drug may be overridden in some situations. For example, a patient might develop unacceptable side effects, an unsatisfactory clinical outcome, or poor adherence. The physician also might need to provide guidance to patients as to whether a nonpreferred drug is worth the higher out-of-pocket cost. In addition, physicians also need to help patients when their drug coverage does not permit them to afford all the prescriptions they need.

TABLE 30-2

Suggestions for Physicians Considering Bedside Rationing

Try to get more resources for the patient within the system.
 Make decisions openly.
 Get a second opinion.
 Notify patients or surrogates when care is rationed.

SUGGESTIONS FOR PHYSICIANS

Physicians who are considering rationing care at the bedside should take several actions (Table 30-2).

TRY TO GET MORE RESOURCES FOR THE PATIENT WITHIN THE SYSTEM

Physicians should try to obtain more resources within the system. For example, in Case 30.1 beds in the postoperative recovery room might be used as temporary ICU beds. Such efforts, however, might lead to other problems, such as disruption of operating room schedules.

MAKE DECISIONS OPENLY

Discussing rationing dilemmas explicitly might identify unquestioned assumptions and hidden value judgments. When people must make their arguments and values explicit, others can present rebuttals or disagreements.

GET A SECOND OPINION

Eliciting a second opinion from another attending physician or from a hospital ethics committee or consultant might improve decision-making. For example, such a review might clarify the patients' prognosis or point out unwarranted value judgments.

NOTIFY PATIENTS OR SURROGATES WHEN CARE IS RATIONED

Patients or their surrogates should be notified when beneficial care will be rationed. It is disrespectful to transfer patients out of intensive care or stop transfusions without explaining to them or their families what is happening. If possible, it is preferable to make such explanations before a clinical crisis occurs.

In summary, bedside rationing might be ethically appropriate if providing services to one patient would directly deprive another patient of services that will provide much greater medical benefits. However, decisions to ration in order to save money might be problematic. Physicians facing such bedside rationing decisions should take steps to help ensure that these decisions are consistent and fair.

REFERENCES

1. Thurow LC. Learning to say "no". *N Engl J Med* 1984;311:1569-1572.
2. Fuchs VR. The "rationing" of medical care. *N Engl J Med* 1984;311:1572-1573.
3. Eddy DM. Rationing by patient choice. *JAMA* 1991;265:105-108.
4. Asch DA, Ubel PA. Rationing by any other name. *N Engl J Med* 1997;336:1668-1671.
5. Ubel PA, Goold S. Recognizing bedside rationing: clear cases and tough calls. *Ann Intern Med* 1997;126:74-80.
6. Schwartz WB. The inevitable failure of current cost-containment strategies. Why they can provide only temporary relief. *JAMA* 1987;257:220-224.
7. Boren SD. I had a tough day today, Hillary. *N Engl J Med* 1994;330:500-502.

8. Pellegrino ED, Thomasma DG. *For the patient's good: the restoration of beneficence in health care*. New York: Oxford University Press, 1988.
9. Kassirer JP. Managing care—should we adopt a new ethic? *N Engl J Med* 1998;339:397–398.
10. Levinsky NG. The doctor's master. *N Engl J Med* 1984;311:1573–1575.
11. Jonsen AR. *The new medicine and the old ethics*. Cambridge: Harvard University Press, 1990:59.
12. Council on Ethical and Judicial Affairs. *Code of medical ethics: current opinions with annotations*. Chicago: American Medical Association, 1998:143.
13. Hillman AL. Managing the physician: rules versus incentives. *Health Aff (Millwood)* 1991;10:138–146.
14. Hall MA. *Making medical spending decisions*. New York: Oxford University Press, 1997.
15. Morreim EH. Fiscal scarcity and the inevitability of bedside budget balancing. *Arch Intern Med* 1989;149:1012–1015.
16. Morreim EH. *Balancing act: the new medical ethics of medicine's new economics*. Boston: Kluwer Academic Publishers, 1991.
17. Ellrodt AG, Conner L, Riedinger M, et al. Measuring and improving physician compliance with clinical practice guidelines. *Ann Intern Med* 1995;122:277–282.
18. Engelhardt HT, Rie MA. Intensive care units, scarce resources, and conflicting principles of justice. *JAMA* 1986;255:1159–1164.
19. Strauss MJ, LoGerfo JP, Yeltatzie JA, et al. Rationing of intensive care unit services: an everyday occurrence. *JAMA* 1986;255:1143–1146.
20. Daniels N. Why saying no to patients in the United States is so hard. *N Engl J Med* 1986;314:1380–1383.
21. Woolhandler S, Himmelstein DU. Costs of care and administration at for-profit and other hospitals in the United States. *N Engl J Med* 1997;336:769–774.
22. Pearson SD. Caring and cost: the challenge for physician advocacy. *Ann Intern Med* 2000;133(2):148–153.

ANNOTATED BIBLIOGRAPHY

1. Levinsky NG. The doctor's master. *N Engl J Med* 1984;311:1573–1575.
Argues eloquently that the physician's primary responsibility is to the individual patient, not to society.
2. Daniels N. Why saying no to patients in the United States is so hard. *N Engl J Med* 1986;314:1380–1383.
Points out that in the U.S. system there is no way to direct money saved on one patient to more cost-effective purposes.
3. Asch DA, Ubel PA. Rationing by any other name. *N Engl J Med* 1997;336:1668–1671.
Clarifies the range of situations in which physicians limit beneficial services because they are too costly.
4. Boren SD. I had a tough day today, Hillary. *N Engl J Med* 1994;330:500–502.
First-person account by medical director of a managed care plan, describing the types of expensive interventions that insurers are asked to cover.
5. Pearson SD. Caring and cost: the challenge for physician advocacy. *Ann Intern Med* 2000;133:148–153.
Suggests criteria for appropriate bedside rationing.

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Incentives for Physicians to Increase Services

Under fee-for-service reimbursement, physicians and health care organizations can increase their incomes by providing more services. They can see more patients, see them more frequently, perform more interventions per patient, and raise their charges for services (1).

PROBLEMS WITH FEE-FOR-SERVICE REIMBURSEMENT

Fee-for-service reimbursement offers incentives to increase all services, not only those services that are effective or cost-effective. Under fee-for-service reimbursement, many earlier studies found extensive overuse of expensive interventions such as carotid endarterectomies, coronary artery bypass operations, and pacemakers (2–5). When patients receive interventions that are unnecessary or of only marginal benefit, they are exposed to unwarranted risks.

Fee-for-service reimbursement also encourages physicians to use invasive procedures rather than to spend time talking with patients about decisions or counseling them about preventive care (6). For example, Medicare reimburses a cardiologist a professional fee of \$445 for inserting a temporary pacemaker, a procedure that takes about 30 minutes. In contrast, Medicare reimbursement for a 1-hour family meeting about withdrawing life-sustaining procedures is \$100. Fee-for-service reimbursement also causes significant conflicts of interest, as discussed next.

SELF-REFERRAL BY PHYSICIANS

Physician self-referral can occur in two ways. First, doctors might invest in freestanding facilities, such as clinical laboratories or radiology services, to which they refer patients. This arrangement is also called a *joint venture*. In the early 1990s, physicians in Florida and several other states owned almost all freestanding radiology centers (7). Second, physicians may carry out radiology imaging or clinical laboratory testing in their own offices. For example, internists commonly carry out and interpret chest x-rays, cardiologists perform echocardiography, and orthopedic surgeons carry out magnetic resonance imaging (MRI) scans. Both types of self-referral raise ethical concerns about overutilization of services and conflicts of interest (8–10).

Empirical studies show that physicians who self-refer in both these ways order significantly more imaging studies and generate higher radiology costs than other physicians (7,8,11). It is believed that many of these additional studies are not warranted. In general, greater use of medical services is not associated with better patient outcomes (12). However, only one study has examined this question directly, finding that the percentage of inappropriate MRI studies was greater when self-referring physicians ordered studies (8).

JUSTIFICATION

Proponents argue that technology misuses claims. For example, physicians located in rural areas.

Advocates argue that they should be able to take such risks.

PROBLEMS

A conflict of interest exists financially. The physician's commitment to the patient is compromised because physicians are not paid for the services they provide.

Even the physician's profession. Accidents should be avoided; it is traditionally the physician's own sake.

Poor quality of care. Deficiencies in care.

PROHIBITIVE

Joint ventures: physicians are not allowed to have a financial interest in Medicare or Medicaid services. Durable medical equipment: physician's office, areas, and similar prohibitions.

Disclosure of conflicts of interest in facilities in which a financial interest exists for testing patients if they are referred.

DISTINGUISHING

Referring patients to distinguished facilities. First, procedures are an integral part of patient and family services that are simply referred.

JUSTIFICATION FOR SELF-REFERRAL

Proponents argue that such physician investment increases access to care because state-of-the-art technology might not be available otherwise (9). The evidence, however, does not support these claims. For example, none of the physician-owned radiation therapy centers in Florida were located in rural areas or inner cities (13).

Advocates argue that if physicians take financial risks when investing in freestanding facilities, they should be able to share in any profits. Physicians might be more willing than other investors to take such risks because they better appreciate the promise of new technologies (9).

PROBLEMS WITH SELF-REFERRAL

A conflict of interest might arise when physicians recommend services from which they profit financially. The American Medical Association (AMA) states that self-referral might "undermine the commitment of physicians to professionalism (9)." Payment to physicians for referring a patient is considered fee-splitting or a kickback. These are considered unethical because those physicians are not being compensated for providing medical services, but only for referring patients to another provider.

Even the appearance that physicians are trying to increase profits might erode trust in the profession. According to the AMA, "There are some activities regarding their patients that physicians should avoid whether or not there is evidence of abuse (9)." Financial reward for physicians is traditionally regarded as a consequence of serving patients, not as a goal to be pursued for its own sake.

Poor quality of care has been documented for radiology studies performed in physicians' offices. Deficiencies have been found in the quality of equipment, images, and interpretations.

PROHIBITIONS ON JOINT VENTURES

Joint ventures have been condemned as a kickback because physicians are profiting from referring a patient for medical services. Federal regulations prohibit physicians from referring Medicare or Medicaid patients to a health care entity in which they or their family members have a financial relationship, such as ownership or investment (14). Moreover, physicians may not bill Medicare for services provided under a prohibited referral, nor may Medicare pay for such services. The prohibition includes clinical laboratory, radiology, prescription drugs, and durable medical equipment. Exceptions are made for ancillary services provided in the physician's office, group medical practices, health maintenance organizations and hospitals, rural areas, and investment in facilities whose stock is publicly traded. Many states have enacted similar prohibitions.

Disclosure of physician ownership of outside facilities is ethically desirable, as with any conflict of interest. However, disclosure does not diminish referrals by physician-investors to outside facilities in which they have a financial interest (15). Even if patients know that the physician has a financial incentive to increase referrals, they might not be able to judge whether recommendations for testing or treatment are sound. In addition, patients might be afraid of offending physicians if they do not go to the facility in question.

DISTINGUISHING SELF-REFERRAL FROM OTHER PRACTICES

Referring patients for tests or treatments carried out by the physician or in the physician's office is distinguished from referral to outside facilities in which the physician has a financial interest (9). First, procedures as endoscopy, bronchoscopy, coronary angiography and angioplasty, and surgery are an integral part of specialist care. It would make little sense for one surgeon to evaluate the patient and then refer the patient to another surgeon for the actual procedure. Also, payment for services that physicians or their staff carry out are distinguished from kickbacks physicians receive for simply referring the patient for a service. Second, obtaining laboratory tests or imaging studies

in the physician's office serves the patient's best interests because it is convenient and enhances continuity of care.

RESPONSES TO SELF-REFERRAL TO IN-OFFICE SERVICES

Although there are no legal prohibitions on physicians' referring patients to ancillary services in their office or clinic, there are ethical concerns about overutilization of services and poor quality of care. With regard to quality of care, insurers and professional organizations have set certification standards for training of physicians and staff, quality control procedures and audits, equipment, technical procedures, and interpretation of images (8). Similarly, clinical laboratories in physicians' offices must meet federal standards for certification. In addition, physicians should involve colleagues in decision-making—for example, presenting cases at conferences (16). Moreover, physicians should not set up equipment and services in their offices if there is no demonstrated need, and they should not carry out procedures if they lack appropriate training and experience.

NONFINANCIAL INCENTIVES TO PROVIDE MORE SERVICES

Social and psychological factors reinforce financial incentives in fee-for-service medicine to provide more services. First, both the public and physicians regard high-technology procedures such as MRI, angioplasty, and endoscopy as the epitome of excellent medical care. The prestige that hospitals and physicians gain by providing these services encourages their wider use. Second, the inherent uncertainty in clinical medicine encourages the use of additional interventions. One response to such uncertainty is to perform an additional test or to try a new drug. Faced with an individual patient, physicians might recommend interventions that they would not recommend as a general clinical guideline (17). Finally, the malpractice system encourages "defensive medicine," the ordering of interventions of small marginal benefit to patients in order to prevent potential lawsuits.

In summary, the fee-for-service reimbursement system encourages physicians to provide more services and in some instances to overuse services. Both health care organizations and individuals need to ensure that clinical decisions are based on patients' best interests, not on their own self-interest.

REFERENCES

1. Roe RB. The UCR boondoggle: a death knell for private practice? *N Engl J Med* 1981;305:41–45.
2. Franks P, Clancy CM, Nutting PA. Gatekeeping revisited—protecting patients from overtreatment. *N Engl J Med* 1992;327:424–429.
3. Brook RH, Park RE, Chassin MR, et al. Predicting the appropriate use of carotid endarterectomy, upper gastrointestinal endoscopy, and coronary angiography. *N Engl J Med* 1990;323:1173–1177.
4. Greenspan AM, Kay HR, Berger BC, et al. Incidence of unwarranted implantation of permanent cardiac pacemakers in a large medical population. *N Engl J Med* 1988;318:158–163.
5. Winslow CM, Josecoff JB, Chassin M, et al. The appropriateness of performing coronary artery bypass surgery. *JAMA* 1989;260:505–509.
6. Hsiao WC, Dunn DL, Verrilli DK. Assessing the implementation of physician payment reform. *N Engl J Med* 1993;328:928–933.
7. Mitchell JM, Scott E. New evidence of the prevalence and scope of physician joint ventures. *JAMA* 1992;268:80–84.
8. Kouri BE, Parsons RG, Alpert HR. Physician self-referral for diagnostic imaging: review of the empiric literature. *Am J Roentgenol* 2002;179(4):843–850.
9. Council on Ethical and Judicial Affairs AMA. Conflicts of interest: physician ownership of medical facilities. *JAMA* 1992;267:2366–2369.
10. Iglehart JK. Efforts to address the problem of physician self-referral. *N Engl J Med* 1991;325:1820–1824.
11. Hillman BJ, Joseph CA, Mabry MR, et al. Frequency and costs of diagnostic imaging in office practice—a comparison of self-referring and radiologist-referring physicians. *N Engl J Med* 1990;323:1604–1608.
12. Wennberg JE, Freeman JL, Shelton RM, et al. Hospital use and mortality among Medicare beneficiaries in Boston and New Haven. *N Engl J Med* 1989;321:1168–1173.
13. Mitchell JM, Sunshine JH. Consequences of physician ownership of health care facilities—joint ventures in radiation therapy. *N Engl J Med* 1992;327:1497–1501.
14. Stout SM, Warner DC. How did physician ownership become a federal case? The Stark Amendments and their prospects. *HEC Forum* 2003;15(2):171–187.

15. Financial arrangements. General, U.S. Dept. of Health and Human Services. *Med* 1990;322:1162.
16. DeMaria AN. Self-referral. *Am J Roentgenol* 1990;154:1162.
17. Redelmeier DA, Tversky A. The psychology of defensive medicine. *Am J Roentgenol* 1990;154:1162.

ANNOTATED BIBLIOGRAPHY

1. Kouri BE, Parsons RG. Physician self-referral for diagnostic imaging: review of the empiric literature. *Am J Roentgenol* 2002;179(4):843–850.

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Incentives for Physicians to Increase Services

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15. *Financial arrangements between physicians and health care businesses*. Washington: Office of the Inspector General, U.S. Dept. of Health and Human Services, 1989.
16. DeMaria AN. Self-referral in cardiology. *J Am Coll Cardiol* 2004;43(8):1500-1501.
17. Redelmeier DA, Tversky A. The discrepancy between medical decisions for individuals and for groups. *N Engl J Med* 1990;322:1162-1164.

ANNOTATED BIBLIOGRAPHY

1. Kouri BE, Parsons RG, Alpert HR. Physician self-referral for diagnostic imaging: review of the empiric literature. *Am J Roentgenol* 2002;179:843-850.
Review of empirical studies of extent and consequences of self-referral for patients.